

**THE IMPLEMENTATION OF AN
INTEGRATED PREVENTION OF
MOTHER-TO-CHILD TRANSMISSION
OF HIV (PMTCT) PROGRAMME AT
McCord Hospital, South Africa,
2003-2013**

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PREAMBLE

DEDICATION

This thesis is dedicated to all the people who worked in the PMTCT programme at McCord Hospital between 2003 and 2013, as well as the women, their partners and children who received care at the hospital, with thanks to the Elizabeth Glaser Peadiatric AIDS Foundation and PEPFAR for the funding of the programme.

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ABSTRACT

Integration is an important emerging health systems issue, which has relevance to different health programmes. Improving prevention of mother-to-child transmission of HIV (PMTCT) programs in South Africa would reduce preventable maternal and infant morbidity and mortality, assist with achieving Millennium Development Goals 4 and 5, and help in the response to the WHO call for the elimination of MTCT, the new international PMTCT goal. Integrating PMTCT care into routine maternal and child health programmes has been recommended as a way to optimize PMTCT care.

The Part B literature review in this dissertation examines the reasons why PMTCT programmes need to engage with integration as an issue, challenges to implementing integrated programmes, followed by a discussion of the benefits and lessons to consider in planning integrated PMTCT programmes. Theoretical concepts and frameworks such as Atun's framework, complexity, Theory of Change and innovation in health systems are discussed, as they have key relevance to the research findings.

Lessons about implementing health system changes can be learned from programmes which have done so successfully. Using Case Study methodology, the process of developing the fully integrated longitudinal clinic at McCord Hospital is described in Part C, and reflections on the experience of providing integrated care are captured through qualitative interviews with the staff. Recommendations regarding innovation and change within complex systems are made, emphasizing the need to understand contexts which are receptive to change and the importance of leadership in managing change.

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Lastly, I would like to thank my friends Tamryn Crankshaw, Lisa Butler, Kathryn Stinson, Penny Morrell, and Claudine Hennessy for taking an interest and walking parts of this road with me.

DECLARATION

I, Janet Giddy (GDDJAN001), hereby declare that the work in this dissertation is based on my original work (except where acknowledgements indicate otherwise) and has not, in whole or in part, been submitted towards another degree, at this University or elsewhere.

I empower the University of Cape Town to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever.

Signed by candidate

Janet Giddy

Date: 30 September 2015

DISSERTATION CONTENTS

Preamble

Part A: Research Protocol

Part B: Literature Review

Part C: Journal Article Manuscript

ACRONYMS AND ABBREVIATIONS

AIDS	Acquired immunodeficiency syndrome
ANC	Antenatal clinic
ART	Antiretroviral therapy
CD4	CD4 T cell lymphocytes: a lab measure of immune function
CDC	Centers for Disease Control and Prevention
CHW	Community health worker
CEO	Chief Executive Officer
DoH	Department of Health
HIV	Human immunodeficiency virus
KZN	KwaZulu-Natal
LMIC	Low and middle-income countries
LTFU	Loss to follow up
MCH	Maternal and Child Health
M&E	Monitoring and Evaluation
MDGs	Millennium Development Goals
MNCH	Maternal Neonatal Child Health
MPI	Male partner involvement
MTCT	Mother-to-child transmission of HIV
MSF	Medicines sans Frontiers
NCCEMD	National Committee for Confidential Enquiries into Maternal Mortality in South Africa
NIMART	Nurse Initiated Management of ART
NVP	Nevirapine

PCR	Polymerase Chain Reaction (infant HIV test)
PEPFAR	President's Emergency Plan for AIDS Relief
PHC	Primary Health Care
PMTCT	Prevention of mother-to-child transmission of HIV
PHC	Primary Health Care
SA	South Africa
SAPMTCT	South African National PMTCT evaluation
SSA	Sub-Saharan Africa
TB	Tuberculosis
ToC	Theory of Change
USAID	United States Agency for International Development
WHO	World Health Organization

MPH Dissertation (FHS015)

PART A: RESEARCH PROTOCOL

HOW TO MAKE THE IDEAL OF INTEGRATION A PRACTICAL REALITY: THE PREVENTION OF MOTHER-TO-CHILD TRANSMISSION OF HIV (PMTCT) PROGRAMME AT McCORD HOSPITAL, DURBAN

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INTRODUCTION

Human immunodeficiency virus (HIV) and related infections are the leading cause of maternal deaths in South Africa (National Committee on Confidential Enquiries into Maternal Deaths 2012). Improving prevention of mother-to-child transmission of HIV (PMTCT) programs in South Africa can result in improving preventable maternal and infant HIV disease morbidity and mortality, and assist with achieving Millennium Development Goals (MDGs) 4 and 5 (Countdown Coverage Writing Group 2008).

Many health care programmes and interventions are delivered as ‘vertical’ services, meaning a narrow, focused programme dealing with a specific health issue (for example tuberculosis, HIV, or maternal and child health) as opposed to comprehensive health care delivery. Integrating the delivery of different health care programmes to create more comprehensive care has been suggested as an efficient and effective way to improve health and decrease health care costs (USAID 2011a). One strategy suggested to reduce maternal and child mortality and to impact the global HIV epidemic is to integrate HIV prevention, treatment and care services with maternal and child health (MCH) care services. However, it is not yet clear from the literature if such strategies are effective (USAID 2011a).

There are many challenges associated with health service integration (Scripitapata 2007, Atun et al 2009, Tudor Car et al 2011, USAID 2011a, Smart 2012). In fact, even the word ‘integration’ has no commonly accepted definition, which makes systematic analysis of the relative merits of integration in different contexts complicated. Some of the problems experienced with integration are related to health systems issues rather than the process of integration itself, and it has therefore been noted that integration should be addressed as part of a wider systems approach to improve health services (Ryman et al 2012).

The literature indicates that there are some advantages to integration, but also disadvantages. Contexts differ and this coupled with variables such as health care personnel and their level of skills, will affect the impact of integration (USAID 2011b).

Integration is an important emerging health systems issue, because it has relevance to different health programmes. Understanding the complexity of issues related to integration in PMTCT programmes will provide insight into broader health system challenges and ways of optimizing care. It is also a relevant health policy and planning concern.

The *South African National Integrated PMTCT Accelerated Plan* of 2011 calls for comprehensive approaches to PMTCT improvement and for the integration of PMTCT into the existing maternal and child health interventions. The issue of integrated health care services is thus very topical in South Africa.

This study will explore a PMTCT programme in South Africa, which implemented HIV care services integrated with MCH services. The process of integrating the services will be described and then assessed retrospectively in order to draw out implementation lessons, which could be useful to PMTCT (and other) programmes planning to integrate services.

McCord Hospital is a state-aided general hospital in Durban, which received external funding starting in 2003 to improve the PMTCT program. In 2004 further funding, via PEPFAR was received to rapidly scale up the treatment of all HIV infected people seeking care at McCord Hospital (Geddes et al 2011).

As a result of the two tranches of funding, the PMTCT programme expanded, and over a number of years developed into a care programme in which HIV care was fully integrated into antenatal care. Comprehensive postnatal integrated care of mother-infant pairs from the time of delivery up to the age of 18 months was later added. This enabled the PMTCT

‘Continuum of Care’ to be more seamless and complete, in an attempt to make the ideal of integrated care into a practical reality.

From 2003 to 2010, the researcher of this proposed study was the director of the McCord Hospital HIV-care programme, which comprised a number of components including pre-antiretroviral therapy (ART) care, ART for adults, ART for children, ART initiated in very ill in-patients, and a PMTCT programme. There was also an active research programme at the hospital and the McCord Hospital Research Ethics Committee provided oversight to the increasing number of research projects, which included basic science, clinical as well social science related research. The researcher was a collaborator in various of these research projects, including a prospective PMTCT research project, which started enrolment in 2010.

After relocating to Cape Town and starting to work for the Western Cape Department of Health in the Khayelitsha and Eastern Sub Structure PMTCT programme in 2012, the researcher noted that maternal and child health services in this public sector context were fragmented with antenatal, delivery and post natal care often provided by different service providers. Provincial and City Health authorities provide antenatal and postnatal care services in Khayelitsha and patients move between them, for various reasons, including the availability of birth services. HIV care was not well integrated with obstetric care, and the post-natal linking of care of HIV exposed infants was very challenging and mother-infant pairs do not receive integrated follow up care.

This practical experience of a large public sector PMTCT programme raised many questions regarding integrated care and the challenges it posed. It highlighted some of the same questions and uncertainties about integrated services as the researcher had experienced previously at McCords. It was the motivation for undertaking this retrospective analysis of

the McCords experience and to evaluate how this might inform other South African health care programmes.

Background

HIV infection in pregnant women: a significant problem

The impact of HIV infection on maternal mortality in South Africa has been enormous. The National Committee for Confidential Enquiries into Maternal Mortality in South Africa (NCCEMD) was established in the 1990s, with the goal of documenting maternal mortality and the reasons for it. The goal of the NCCEMD is to identify substandard care, to enable improvements in health care delivery to be recommended. It issues triennial reports and the 2008-2010 Saving Mothers Report (National Committee on Confidential Enquiries into Maternal Deaths 2012) notes that 40.5 % of all maternal deaths are caused by HIV and related infections, making this the leading cause of maternal deaths in South Africa.

Of South Africa's nine provinces, KwaZulu-Natal (KZN) has the highest overall HIV prevalence in pregnant women at 37.4%, according to the 2012 *National Antenatal Sentinel HIV and Syphilis Prevalence Survey* (South African Department of Health 2012), which also shows that nationally, 29.5% of pregnant women are HIV-infected. According to Rollins et al (2007), without any PMTCT intervention, mother-to-child (MTC) HIV transmission rates in South Africa approach 34% by 18 months of age. The overall MTC transmission risk in KZN prior to the introduction of the 2010 PMTCT guidelines was between 18 and 22%, which resulted in an estimated 30,000 perinatal HIV infections annually (Rollins 2007, Doherty et al 2003). South Africa is one of only 9 countries in the world where the child mortality rate is increasing instead of decreasing, mainly as a result of children dying of AIDS-related illnesses. High rates of maternal and infant loss to follow-up are commonly reported by PMTCT programs in South Africa and can result in preventable maternal and infant HIV

disease complications (Sherman et al 2004, Coetzee et al 2005, Doherty et al 2003, Colvin et al 2007).

In addition to concerns about women's continued health, evidence suggests that a baby's survival and wellbeing are intrinsically linked to the mother's wellbeing (Obimbo et al 2004, Brahmbhatt et al 2006, Rich et al 2006, Marinda et al 2007). Multiple studies have shown that maternal morbidity and mortality are associated with increased infant morbidity and mortality (Rich et al 2006, Marinda et al 2007, Newell et al 2004). These studies show that interventions to support maternal health are likely to reduce infant morbidity and mortality, regardless of those infants' HIV status.

The high rate of attrition from PMTCT cohorts is multi-factorial. Non-disclosure of HIV status, lack of integration of HIV services and the fact that studies have shown that women accessing PMTCT services generally seem to consider it an entry point of care for their infants but not themselves (Newell et al 2004) are amongst some of the underlying reasons.

Integrating health care services

While it is difficult as health care providers to significantly address the issues surrounding non-disclosure (which include ongoing HIV related stigma), the issue highlighted by Newell et al regarding lack of integrated services is also referred to in the United States Agency for International Development (USAID) report (2011a). Integration of services is more amenable to health service interventions than addressing non-disclosure and stigma.

Integration has become a buzz word in last few years amongst public health specialists, politicians and international health experts: guidelines issued by the World Health Organization (WHO) recommend integrating PMTCT within Maternal Neonatal Child Health (MNCH) services to ensure optimal care (USAID 2011a). However, the notion of integration

as a way to improve the provision of health care, including maternal and childcare provision, is not a new one. The Alma Ata Declaration in 1978 (WHO 1978) was the first international document to highlight the importance of Primary Health Care (PHC). Section 7 lists the components of PHC. The 6th component refers to comprehensive health care, which includes the word ‘integrated’ as one of the defining features of comprehensive care. In reference to MNCH services the WHO recommends: “Integration of HIV interventions into maternal, newborn and child health (MNCH) services involves the reorganization and reorientation of health systems to ensure the delivery of a set of essential interventions for HIV prevention, treatment and care as part of the continuum of care for women, newborn, children and families” (WHO 2006).

Integration of PMTCT programmes with MNCH services

PMTCT is a very important component of MNCH services, but HIV care and treatment services have generally been developed as stand-alone clinical services, often with limited integration with maternal health services (Abrams et al 2007). This separation has resulted in HIV and MNCH services either being provided in different clinics or in the same clinic by different providers. This separation of care for pregnant women prevents both services from achieving optimal clinical outcomes, as noted by Levy (2009), writing about woman’s expectations of treatment and care after an antenatal HIV diagnosis in Malawi. In her study PMTCT care, antenatal, delivery and outpatient care were all provided separately, in the same facility, while antiretroviral therapy was provided at a separate site. The study found that the health care provided did not meet the expectations of the pregnant women, and one of the reasons given was the lack of integrated care. Levy concluded that women's own health was marginalized within the PMTCT programme, and recommended that integrating with other health services would move the PMTCT programme beyond its focus on infants

alone to encompass women's health, recognizing that infant survival is crucially dependent on this.

Baek and Rutenberg (2010) conducted operational research to determine how interventions successful in clinical trial conditions could be adapted to the real-world maternal and child health care services in low-resource settings. A key finding from interviews with service providers and HIV-positive women in developing countries including South Africa, was that PMTCT programmes should strengthen the links between ANC, delivery, child health, and HIV services and they concluded with a call to strengthen ties between PMTCT services and HIV care and treatment programs.

This recommendation is echoed by Sripipatana et al (2007) who assessed a variety of interventions to improve PMTCT programs in less developed settings and recommended that in order to ensure integration, PMTCT services should be provided by the regular maternal and child health (MCH) staff, not by a separate cadre of health care providers.

PMTCT programs can be viewed as a gateway to family-based HIV care and treatment (Abrams et al 2007). There is a strong rationale for linking PMTCT and HIV care and treatment services, in the opinion of the authors, as significant benefits can be anticipated, resulting in markedly decreased morbidity and mortality for women, their children, and their families.

The benefits of integrating PMTCT services with MNCH services

The Millennium Development Goals (MDGs) are 8 international development goals, established at the Millennium Summit of the United Nations (UN) in 2000. All 189 UN member states at that time and many international organizations committed to help achieve these goals by 2015. MDG goals 4 and 5 relate to improving maternal and child health and

decreasing mortality (Countdown Coverage Writing Group 2008). Providing good quality PMTCT therefore directly impacts the achievement of the MDGs. The 2008 report on the countdown to 2015 (Countdown 2008) for maternal, newborn, and child survival which tracks coverage of interventions to achieving MDG goals 4 and 5, highlighted that opportunities to increase coverage through combined delivery of interventions have been missed. The authors of the report noted that programmatic links between different elements of the continuum of care for maternal newborn, and child health frequently are not being promoted or provided.

In May 2009, President Barack Obama announced in his Global Health Initiative “we will not be successful in our efforts to end deaths from AIDS, Malaria and tuberculosis unless we do more to improve health systems around the world, focus our efforts on child and maternal health, and ensure that best practices drive the funding for these programs” (USAID 2011a). Many governments are responding to the continuing HIV pandemic in developing countries by seeking policies and strategies to increase access to and quality of MNCH services as a way to improve the health of women and children, reduce maternal and infant mortality and morbidity, and improve pregnancy outcomes. One of these strategies is the integration of services traditionally provided separately: MNCH and PMTCT (USAID 2011a).

The vision for integration calls for inclusion of PMTCT interventions within the full continuum of existing public, private, and community-based MNCH health services, as well as sexual and reproductive health programmes (USAID 2011a). The rationale for integrating PMTCT interventions with MNCH services include the high burden and risk of HIV infection among pregnant women in Africa and the inherent biological and clinical relationship between HIV and sexual and reproductive health (USAID 2011a).

In summary, the mooted benefits of providing integrated care include: improving maternal health care, including retention in care (Newell 2004); improving clinical outcomes and reducing morbidity and mortality in women and their children (Abrams 2007); responding to the expectations of pregnant women (Levy 2009); providing comprehensive care (Alma Ata Declaration 1978); and the achievement of the MDG's (Countdown Coverage Writing Group 2008). Other reasons proposed are that integrated services have the potential to increase service utilization and educe stigma of certain services (Ryman et al 2012).

Models of providing integrated care

There are the different models of integrated care. For example one provider might offer a full range of services (often termed 'room-level' or 'provider-level' integration, as a 'one stop shop' service), or clients are referred to a more specialized provider within the same facility (termed 'facility-level' integration or 'integration under one roof') versus clients being referred to other specialized facilities for certain services (Church and Mayhew 2009). These different models will be unpacked and explored in the course of this study.

Challenges to the notion of integration

While the actual or anticipated advantages of integrating programmes that focus on specific interventions (PMTCT or immunization or reproductive health) into health systems have been clearly stated, the benefits of integration to improve specific outcomes has also been challenged by Atun, a major theorist on integration, as well as others. The fact that the word 'integration' has no commonly accepted definition makes systematic analysis of the relative merits of integration in different contexts complicated (Atun et al 2009). Clements et al (2008) also sound a note of caution about the challenges of integration with the statement "integration has been the frustrated rally call of Primary Health Care for 30 years."

The integration debate has been driven by a binary approach of comparing of non-integrated ('vertical') versus integrated ('horizontal') programmes in a narrow way with protagonists in favor or against each approach arguing in a polarized way, according to Atun et al (2009). An ever expanding lexicon of terms has also emerged, for example targeted programmes emphasizing specific interventions have been referred to as 'vertical', 'categorical' or 'stand alone', while programmes with elements which are more integrated into health systems have been called 'horizontal' or 'integrated health services'. Terms such as 'diagonal' or 'oblique' have been used to describe approaches which are not narrowly vertical nor fully integrated. Atun et al also note that the fact that many countries use both integrated and non-integrated programmes suggests that both approaches have merits.

Atun et al's 2009 paper presents a useful conceptual analytical framework which enables deconstruction of the term integration into multiple facets, each corresponding to a critical health system function, that include financing, governance, planning, service delivery and monitoring and evaluation.

The challenges and problems of how to integrate services in practice have been documented (Tudor Car 2011, Atun et al 2009, Smart 2012). The push to integrate is sometimes externally driven and is the result of less donor money and the need to expand the reach and uptake of services such as ART and to make essential services more convenient for clients (Smart 2012).

Integrating programmes does not always have a positive outcome - efficiency may not increase and the quality of care may suffer. There are also 'costs' related to integrating services. Smart (2012) notes that integration may lead to improved health of patients, and increased efficiency in the health system, but that there are significant implications for staff

workload, as well as a need for training. Integration may thus lead to task shifting, which needs to be actively managed.

This is echoed by Scripitapata (2007), who cautions that adding PMTCT services will increase the time demands on staff, and that additional personnel may be required to handle the workload. Equally important, all staff in the facility must be appropriately trained in PMTCT. The addition of counselling alters patient flow and creates a need for confidential space.

Some of the problems experienced with integration are related to health system issues rather than integration, and should be addressed as part of a wider approach to improve health services (Ryman et al 2012). It has been suggested that improved planning and patient flow, as well as increasing the number of health staff and providing training would help to mitigate logistical challenges of integrating services (Winestone 2012).

Experiences of providing integrated care in PHC services: general

The experiences of integrating various components of primary care services has been studied in other primary care programmes, such as immunization and sexual and reproductive health (SRH). Various studies have assessed the potential to improve the coverage of multiple health interventions through integrating delivery with routine childhood vaccination (Clements et al 2008, Anand et al 2012, Ryman et al 2012). The findings indicate that where the health system is struggling, adding another intervention onto an immunization service might be the straw that breaks it's back. However, in contexts where the health system is strong, routine clinical contacts such as vaccination may be excellent opportunities for additional child survival interventions (Clements et al 2008).

The integration of general HIV services (other than PMTCT) with other primary care services has yielded mixed outcomes. The integration of a variety of primary care services with HIV voluntary counseling and testing in Haiti was positively reported by Peck et al (2003). A systematic review of SRH-HIV linkage interventions (Kennedy et al 2010) found that were generally considered beneficial and feasible, and most studies showed improvements in all outcomes measured. While there were some mixed results, there were very few negative findings while positive effects were shown for key outcomes, including HIV incidence, sexually transmitted infection incidence, condom use, contraceptive use, uptake of HIV testing and quality of services.

The impact of integration of STI and HIV care into family planning services on five specific outcomes was evaluated by Church and Mayhew (2009), who found overall that the evidence of the benefits of service integration was mixed for most of the outcomes. Many of the challenges related to weaknesses of health systems in general and were not specific to reproductive health care, but were problems related to human resources, facility infrastructure, logistics, medical education and training, and service management. Successful program improvements were attributed to sufficient time being taken to establish and support integrated service delivery and set up the necessary systems in developing countries.

Experiences of providing integrated PMTCT programmes in Africa

Studies assessing the benefits of integration in PMTCT programmes in Africa reported predominantly positive findings (Killam et al 2010, Kasenga 2010, Tsague et al 2010, Odero Ong'ech 2012). The benefits of integration covered a spectrum of findings, including important outcomes such as significantly increasing the enrolment of HIV infected women into ART care (Tsague et al 2010, Killam et al 2010), as well as better follow up of HIV-exposed infants (Odero Ong'ech 2012).

The views of healthcare providers regarding integrating HIV care services into antenatal care clinics noted advantages such as decreased patient waiting time, increased efficiency and improved provider-patient relationships, which all contributed to increased patient satisfaction (Winestone et al 2012, Vo et al 2012).

Given the variety of views and findings regarding the benefits and disadvantages of integration, this has been a topic of systematic reviews. There have been 3 Cochrane systematic reviews (Dudley and Garner 2011, Tudor Car et al 2011, Lindegren et al 2012) evaluating strategies for integrating primary health services in low-and middle-income countries. The results were mixed, but the review by Lindegren et al (2012) which evaluated integrated HIV and MNCHN-FP services showed that it was feasible to implement integrated programmes and that they showed promise towards improving a variety of health and behavioral outcomes.

The need for more research into integration of services

If there is one topic which most authors (Abrams et al 2007, Atun et al 2009, Church and Mayhew 2009, Kennedy et al 2010, USAID 2011, Dudley and Garner 2011, Tudor Car et al 2011, Anand 2012, Dudley and Lindegren et al 2102) agree on, it is that there is a need for more research into integration, including how it should be implemented in practice. There is a dearth of strong study designs related to research on integration of services, despite calls to increase the strength of evidence on this topic.

The Current South African Context

The South African National Integrated PMTCT Accelerated Plan of 2011 calls for comprehensive approaches to PMTCT improvement and for the integration of PMTCT into the existing MCH interventions such as basic antenatal care, integrated management of

childhood illnesses, expanded programme on immunization and sexual and reproductive health, and to ensure that HIV infected mothers and babies are appropriately referred to HIV services for continued treatment, care and support (Department of Health National Integrated PMTCT Accelerated Plan, 2011).

Currently this is an aspirational recommendation, given that the practicalities of how it will be translated into reality, and what the challenges might be and how to address them, is not clearly spelled out. Horwood et al (2010) showed in a South African study that there was a high coverage of PMTCT interventions during pregnancy and delivery, but follow-up of mothers and infants was poor. Poor integration of PMTCT services into routine care, lack of clarity about health worker roles and poor record keeping create barriers to accessing services post delivery

There has been limited operational research on programmes which have implemented integrated PMTCT services, particularly the follow up of mother-infant pairs in South Africa. There are very few examples of a PMTCT programme with a delivery care model including 18 month post natal care, such as that provided at the McCord Mamanengane clinic. Therefore, an evaluation of the McCord PMTCT programme could provide useful information on the experience of implementing integrated care for pregnant women and their infants in South Africa. The next challenge would be to evaluate how the lessons could be rolled out in a bigger public sector context, particularly in a complex health systems contexts. This research will therefore address the call in the literature for more studies looking at integration in low and middle income countries.

PURPOSE OF THE STUDY

The purpose of this study is to retrospectively describe the McCord Hospital model of integrated care and to explore how it was implemented. The goal would be to assess what historical lessons can be drawn from the McCord experience that might have value to addressing challenges to providing more integrated PMTCT care, for example in the Khayelitsha context.

RESEARCH QUESTION

What was the McCord Hospital model of integrated PMTCT care? How and why was it implemented? How can lessons from understanding staff perception about the integrated care program inform wider health care programmes?

SUB-QUESTIONS

- What model of PMTCT care was initially implemented?
- By the end of the project, what model of integrated care developed?
- How did the staff working in the PMTCT programme understand the concept of integrated care?
- What did the staff see as the advantages or challenges of integrated care?
- What did they think were enabling factors?
- How did they think obstacles could be overcome?

THE FRAMEWORK

The framework to be used in this study would be an exploratory case study, focused on one site, utilizing process evaluation tools to understand the integration process. Qualitative and historical methodology will be utilized to develop the case.

METHODOLOGY

Case study methodology will be used. This is a methodology which enables the researcher to answer “how” and “why” type questions, while taking into consideration how a phenomenon is influenced by the context within which it is situated (Baxter and Jack 2008).

Case study research comprises “an empirical investigation into a contemporary phenomenon within real life, using multiple sources of data” (Yin 1984). It focuses on a single case (or several cases) which are situated in a specific social and physical setting. It is useful as an exploratory or explanatory strategy and shows the multiple contextual factors which influence the working of health systems (Gilson 2011). This will be a historical case study.

The use of qualitative case studies support the deconstruction and the subsequent reconstruction of various phenomena, and is a useful for health science research to develop theory, evaluate programs, and develop interventions, because of its flexibility and rigor. The use of multiple sources of data ensures that the issue is not explored through one lens, but rather a variety of lenses which allows for multiple facets of the phenomenon to be revealed and understood (Baxter and Jack 2008).

Case studies of facilities or programmes and the people within them are useful to identify the many potential influences, and which factors are particularly important, to examine inter-

relationships (complex causality) and to generate ‘theory’ which can be further tested through future work (Baxter and Jack 2008).

the starting point will be to do a scoping literature review and analysis on how ‘integration’ is currently understood and described in different contexts. The McCord case study will then be described, and an analysis done with some theory building.

The case is the McCord Hospital PMTCT programme, which was purposively selected because of the integrated model of care which was implemented in 2008. The PMTCT programme (along with the whole comprehensive HIV programme at McCord Hospital) ended in 2013 when PEPFAR funding was withdrawn and the KZN Department of Health did not take over the funding of the McCord HIV programmes as had been expected.

This is a sub-study, drawing from a broader programme of research in which the researcher was involved while working with the McCord Hospital PMTCT programme. Three retrospective evaluations of the McCord PMTCT programme have already been published (Geddes et al 2008 and 2011, Chetty et al 2012). A prospective study to evaluate the programme started in January 2010, and the researcher was a member of the research team, which included an international collaborator (based at the University of California, San Francisco), as well as the PMTCT programme manager at the time. One of the components of the evaluation, in addition to the clinical outcomes, was a series of qualitative interviews with staff to assess their views and perceptions regarding the programme. These interviews were conducted by a research assistant in 2012, after the clinical data was collected. They have not yet been analyzed, as the research analysis thus far has focused on the clinical outcomes.

This sub-level case study will draw from a variety of information sources with the main emphasis being an analysis of the staff interviews conducted in 2012. The researcher will perform this analysis (for the purpose of this study), and in order to ensure trustworthiness of

the data, will also discuss the findings with the other two members of the original research team.¹ The researcher will do the primary data analysis and coding of the McCord interviews, and these collaborators will act in an advisory capacity to reflect on analysis results and findings. They will be co-authors on any papers published using the McCord data *after* this thesis publication.

In addition to the findings of these qualitative interviews, the researcher will refer to articles written about the McCord PMTCT programme (Geddes et al 2008 and 2011, Chetty et al 2012). She will also draw on her knowledge and experience of the programme as well as referring to existing documentation (such as treatment protocols, minutes of meetings, and reports to funders).

Therefore, in this case study, a variety of methods will be applied for data collection and cross-analysis, including qualitative data from the staff interviews. The researcher's own knowledge and experience (observation) will also be included.

The integrated longitudinal care model of the McCord PMTCT programme is an unusual, 'exceptional' example of a PMTCT programme in South Africa. Exceptional cases are valuable as they may provide new insight into a problem or new leads for further inquiry (Baxter and Jack 2008)

In-depth Interviews

Semi structured interviews were conducted in 2012 with the 7 staff members involved in the PMTCT programme in different capacities and roles, including counselors, nurse clinicians, a doctor and the programme manager. The analysis of these face to face interviews will allow

¹ These other researchers are both experienced in qualitative research. They are T. Crankshaw (PhD), a previous McCord Hospital PMTCT Program manager, and LM Butler (PhD, MPH), a researcher from the University of California, San Francisco.

the researchers to elicit detailed responses to provide the data to answer the research questions.

A semi structured interview guide was used in the interviews – see Appendix 1, with the interviews conducted by an experienced field worker. Certain questions were more relevant to certain categories of staff, for example, questions to managers were slightly different to questions asked to nurse clinicians. Where necessary, the interviewer asked additional questions and questions related to clarity even if they were not included in the questionnaire. The interviewer also gave study participants an opportunity to talk about any issues which they felt were important. In this way the research participants could discuss more personal opinions which may not have been covered by the pre-determined questions. Each interview lasted for approximately one hour and was conducted in English. As they were professional staff, the interviewees were all fluent in English. The interviews were held in a private room at the facility, and were audio taped and transcribed verbatim. The analysis that will be conducted in this research study will be based on these transcriptions and audio files.

Data Management

All field notes and audio recordings of all interview and transcripts are in an electronic format. They are stored on the computers of the researchers which are password protected. Data also includes typed transcripts, and audio cassette tapes. Each data collection event was assigned a unique code and once transcribed included a physical paper copy and an electronic copy stored on the researcher's computer. All other forms such as questionnaires, interview guides, informed consent forms and any other materials necessary are also available in two formats and are stored in the researcher's office.

Data Analysis

Parallel streams of data analysis will be conducted and integrated. Thematic analysis (searching for themes) will be conducted across the variety of primary and secondary documentation (from the literature review and from the programme documentation). At the same time thematic analysis will be conducted of the McCord interview transcripts. These parallel streams of analysis will feed into each other, and at the end of the study will be properly integrated. Qualitative analysis emphasizes how data fit together to make a whole, and includes context and meaning because social phenomenon cannot be understood outside of the context in which they are located. Therefore, ‘constant comparative analysis’ will be used in the analysis process (Attride-Stirling 2001). This is a way to identify patterns and commonalities in the thoughts, perceptions and practices of study participants. It begins with immersion by reading and rereading transcripts looking for emerging themes, which are common strands of ideas / issues which are found in what the subjects talk about (Attride-Stirling 2001). See Appendix 3 for a summary of the steps involved in thematic analysis. After the themes have been analyzed, a conceptual diagram will be created to illustrate the findings and relationships between them

The researcher will be hand coding the themes, not using a computer software programme for this. Data analysis will initially be done by the researcher and the findings subsequently discussed with the other two members of the McCord research team. This will ensure better reflexivity.

Reflexivity

The researcher previously worked in the McCord Hospital HIV and PMTCT programme. In order to be aware of her own views and biases regarding the topic and as well as her relationships with the staff, the researcher needs to exercise constant reflexivity. She will do so by ensuring by having several debriefing sessions with her supervisor in which analysis and findings will be considered.

ETHICS

Permission was obtained from the McCord Hospital Research Ethics committee to conduct the seven in-depth interviews of PMTCT programme staff to evaluate the impact and implementation of the integrated post natal PMTCT programme, as part of a broad PMTCT programme evaluation in 2012. The study participants gave full consent (see Appendix 3) and the study was considered to be minimal risk for the participants. The letter of approval from the McCord Hospital Research Ethics Committee is attached in Appendix 4.

The study will also be submitted to the UCT Health Sciences Ethics Committee, and full ethical considerations will be upheld (for example in terms of anonymity and security of data), although this is a retrospective sub-study. This sub-study is considered to be low risk – as it mainly involves secondary and documentary analysis, and participants will remain anonymous. As the McCord PMTCT programme no longer exists and the staff have left the hospital to take up other work positions, there is no risk that any information they have shared could impact negatively on their work.

The study participants cannot benefit directly as they are no longer working in the programme. The benefit of the study is that lessons learned will be shared with other PMTCT

programmes, as well as general health service providers who are considering providing integrated clinical care.

BUDGET AND COSTS

The McCord Hospital PMTCT programme used a research budget to conduct the PMTCT research. The field worker who did the interviews was paid from this budget. There are no other costs for this current sub-study.

STUDY TIMELINE

The anticipated timeline is presented below:

Activity	Expected Timeline
Submission of protocol and obtaining Ethics (IRB) approval at UCT	Sept – Nov 2014 3 month
Data analysis	Nov – Feb 2014 2 months
Preparation of reports, manuscripts, and presentations	Feb – March 2014 2 month
TOTAL	7 months

WRITE UP AND DISSEMINATION

The findings of the study will be written up as an article as part of the MPH dissertation requirements. Feedback will be given to the study participants who request it, the McCord Hospital Management and PEPFAR / CDC who funded the PMTCT programme at McCords. The findings will also be presented at relevant conferences and workshops, such as the National South African AIDS conference. The article that will be written for publication in a peer reviewed journal will be targeted at a journal focusing on health systems or policy implementation science.

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PART B: LITERATURE REVIEW

INTEGRATING PREVENTION OF MOTHER-TO-CHILD TRANSMISSION OF HIV (PMTCT) PROGRAMMES WITH MATERNAL AND CHILD HEALTH SERVICES: WHY AND HOW TO DO IT

Janet Giddy

GDDJAN001

INTRODUCTION

The Millennium Development Goals (MDGs) established at the Millennium Summit of the United Nations (UN) in 2000, were supposed to be completed in 2015. MDG goals 4 and 5 relate to improving maternal and child health and decreasing mortality (Countdown Coverage Writing Group (CCWG) 2008). Providing good quality prevention of mother-to-child HIV transmission (PMTCT) directly impacts the achievement of the MDGs. The 2008 report (CCWG 2008) which tracks coverage of interventions to achieving MDG goals 4 and 5, highlighted that opportunities to increase coverage through combined delivery of interventions (providing integrated care) have been missed. The authors of the 2008 Countdown report noted that links between different elements of the continuum of care for maternal newborn, and child health frequently are not being promoted or provided, so fragmented rather than integrated care is provided.

One strategy suggested to reduce maternal and child mortality and to impact the global HIV epidemic is to integrate HIV prevention, treatment and care services with maternal and child health (MCH) care services (USAID 2011a)

South Africa, one the countries worst affected by HIV globally, reaffirmed in the 2015 National Consolidated Guidelines (Department of Health 2015), the original call for the integration of PMTCT into existing Maternal and Child Health (MCH) programmes made in 2011 (Department of Health 2011).

This purpose of this literature review is to consider the health system implications of innovations such as integrating PMTCT programmes with MCH services. The reasons for a call to integrate will be explored as well as how to address the challenges related to introducing innovation and change in complex health care systems.

METHODS

A scoping literature review was conducted between 2013 to 2015 using the following databases: Medline, PubMed, Plosmed, Cochrane Reviews and Google Scholar. The initial search was done using a combination of the terms: ‘integration’, ‘health care programme/s’, ‘health care system/s’, ‘primary health care’, ‘HIV’, ‘HIV infected’, ‘HIV-exposed’, ‘prevention of mother-to-child HIV transmission’, ‘PMTCT’, ‘pregnant women’ ‘infants’ and ‘children’, ‘innovation in health care systems’, and ‘change in health care systems’.

Further articles were obtained because they were referenced in the literature or were recommended by colleagues and research collaborators at McCord Hospital and public health colleagues at the University of Cape Town.

The original search was limited to studies published in English from January 2000 (when PMTCT became more widely available, including in Sub-Saharan Africa) to 2015. In studies, participants included pregnant, breastfeeding women and/or mothers living with HIV and their children. Later the search was expanded to articles referring to integration in primary health care contexts, innovation, theory of change and complexity in health care systems. The time-frame for these more specific articles of direct relevance was The dates for articles related to these latter topics were pushed back into the 1990s.

A total of 78 articles were reviewed and the 57 referenced in this literature review were found to be directly relevant, because they included findings relating to PMTCT, specifically in sub-Saharan Africa, integration in primary health care services, and lastly change, innovation and complexity in health care systems.

This literature review will first discuss the reasons why PMTCT programmes need to engage with integration as an issue, challenges to the implementation of integrated PMTCT

programmes, followed by a discussion of the key benefits and lessons to consider in planning integrated programmes. It will then move on to theoretical concepts and frameworks that have key relevance (based on this scoping review) to the research that follows. These include Atun's framework, complexity, Theory of Change and innovation in health systems.

RESULTS

Why PMTCT Programmes Need to Engage with the Issue of Integration

PMTCT programmes are a global HIV success story (UNAIDS 2013, Turan et al 2015). They are deemed to be a cost effective intervention that provide a measureable reduction in HIV transmission (Killam et al 2010, Goga et al 2012). As such, there has been a global push to ensure that they are resourced and supported, which has borne remarkable results: for example, since 2001 accelerated efforts have resulted in a 52% decrease in new infections among children (UNAIDS 2013). In 2010 the first national evaluation of the PMTCT programme in South Africa, showed that the National PMTCT Programme resulted in an average 3.5% MTCT rate (the range in different provinces was from 1.4% - 5.9%) at 6 weeks of age. This is a reduction from the approximately 30% transmission that would occur in the absence of PMTCT interventions, and the estimated 8 – 22% MTCT rate in the early 2000's as the National PMTCT programme was being implemented (Goga et al 2012).

Health care services are often delivered as 'vertical' services, which means a "stand alone" focused programme dealing with a specific health issue (such as tuberculosis or HIV or Family Planning) as opposed to comprehensive health care delivery, in which a programme (such as MCH) provides a broad range of related services. Integrating the delivery of different health care services to create more comprehensive care has been recommended as a

way to improve health and decrease health care costs (USAID 2011a). PMTCT was originally introduced as a vertical service in South Africa (Burton et al 2012).

The motivation to integrate is often externally driven, for example, when there is less donor money for programmes, coupled with the need to expand the reach and uptake of services such as ART and to make essential services more convenient for clients (Smart 2012).

The Challenges of Integrating Health Service Programmes

The challenges, problems and costs of implementing integrated services have been well described (Tudor Car 2011, Atun et al 2009, Smart 2012, Stinson et al 2014).

In the literature, it has also been noted that integrating programmes may result in less efficiency and the quality of care may suffer (Smart 2012). There are often significant implications for staffing - additional personnel may need to be employed, or task shifting may be required to handle the workload, and there will be a need for appropriate training (Smart 2012, Scripita 2007). It has been observed that improved planning and patient flow, as well as increasing the number of health staff and providing training could help to mitigate logistical challenges of integrating services (Winestone 2012).

Some of the challenges relating to integration stem from the underlying health system in which the intervention is implemented and should be addressed as part of a wider approach to improve health services (Ryman et al 2012). The experiences of integrating various components of primary care services has been studied in other primary care programmes, such as immunization and sexual and reproductive health (Clements et al 2008, Anand et al 2012, Ryman et al 2012). The findings indicate that where the health system is struggling, adding another intervention (such integration) might be the straw that breaks it's back

(Church and Mayhew 2009, Clements et al 2008), because of problems related to human resources, facility infrastructure, logistics, training, and service management.

Church and Mayhew (2009) observe that in developing countries, successful programme integration was attributed to sufficient time being taken to establish and support integrated service delivery and set up the necessary systems.

The Advantages of Integrated PMTCT Programmes

While it is acknowledged in the literature that there may be a degree of equipoise about the advantages and disadvantages of integration of programmes at primary care level, many studies, have demonstrated significant advantages to integrated PMTCT programmes.

The reported benefits of providing integrated care for PMTCT programmes include improving maternal health care, better retention in care (Newell 2004); improving clinical outcomes and reducing morbidity and mortality in women and their children (Abrams 2007, Stinson et al 2014); responding to the expectations of pregnant women (Levy 2009); providing comprehensive care (WHO 1978 Alma Ata Declaration); and the achievement of the MDG's (CCWG 2008); and increased service utilization and reduction of HIV related stigma in certain services (Ryman et al 2012).

Studies assessing the benefits of integration in PMTCT programmes in Africa reported predominantly positive findings (Killam et al 2010, Kasenga 2010, Tsague et al 2010, Odero Ong'ech 2012, Stinson et al 2014). The benefits of integration covers a spectrum of findings, including important outcomes such as significantly increasing the enrolment of HIV infected women into ART care (see Tsague et al 2010, Killam et al 2010, Stinson et al 2014), as well as better follow up of HIV-exposed infants (Odero Ong'ech 2012).

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The views of healthcare providers regarding integrating HIV care services into antenatal care clinics highlighted advantages such as decreased patient waiting time, increased efficiency and improved provider-patient relationships, which all contributed to increased patient satisfaction (Winestone et al 2012, Vo et al 2012).

Researching Integrated Programmes

Given the varied views and findings regarding the benefits and challenges of integration, this has been the subject of three Cochrane systematic reviews (Dudley and Garner 2011, Tudor Car et al 2011, Lindegren et al 2012) who evaluated strategies for integrating primary health services in low and middle-income countries. The results are mainly mixed, and contributed to the call by other authors for more research into integration, including how it should be implemented in practice (see Abrams et al 2007, Atun et al 2009, Church and Mayhew 2009, Kennedy et al 2010, USAID 2011, Dudley and Garner 2011, Tudor Car et al 2011, Anand 2012, Lindegren et al 2102). There has been a dearth of strongly evidenced research on the effects of the integration of services, and insufficient robust study designs to support such research.

The Study of HIV and Antenatal care Integration in Pregnancy (SHAIP) was the first randomized trial of integrated ANC and HIV services conducted in rural Africa (Turan et al 2012, and 2015). SHAIP aimed to gather more rigorous evidence on the benefits of integration, and to answer the outstanding questions regarding the feasibility, value and effectiveness of providing integrated PMTCT care, particularly in low resource settings. SHAIP was a prospective cluster randomized controlled trial in which 12 Kenyan government health facilities were randomized to provide either fully integrated services (ANC, PMTCT, and HIV treatment services all delivered in the ANC clinic) or non-integrated services (ANC clinics provided ANC and basic PMTCT services with women

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referred to a separate HIV clinic for HIV treatment). The study enrolled 1,172 HIV-positive pregnant women with the main study outcomes being rates of maternal enrollment in HIV care and treatment and infant HIV testing uptake.

The results of the SHAIIP study published in May 2015 found a significantly positive outcome of increased HIV care enrollment and ART uptake of pregnant women in the integrated study arm. Given the advantages of ART for PMTCT and maternal health, this should not be taken lightly. However, PMTCT utilization outcomes for the duration of the PMTCT cascade were still suboptimal and despite the convenience and benefit of being offered concurrent enrollment for HIV and ANC care, attrition of women and infants over the course of pregnancy and postpartum remained significant, with early infant diagnosis a challenge in both study arms. The study concludes that further improvements in the PMTCT cascade will require additional research and interventions (Turan et al 2015).

Lessons to Consider in Planning for Integrated PMTCT Care

The dominant framework for providing HIV services has traditionally been the ‘continuum of care’ or ‘treatment cascade’, which is a clinical and preplanned patient care pathway (Hsieh et al 2014). It has also been the dominant modality for measuring effectiveness of HIV care, with viral suppression viewed as the optimum marker of success. The stages of a PMTCT ‘continuum of care’ include the initial antenatal care (ANC) visit; HIV testing; HIV diagnosis and treatment for HIV infected pregnant woman; prophylaxis and final infant diagnosis; and linking infants infected with HIV to ongoing ART care and treatment services.

Hsieh et al (2014) caution that current approaches to PMTCT assume a linearity and universality, which result in significant challenges to optimal care, and that most PMTCT programmes in Sub-Saharan Africa do not adequately provide interventions that comprehensively address the varying needs of clients. The consequences of this are high

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levels of loss-to-follow-up at each step of the PMTCT cascade and can result in preventable maternal and infant HIV disease complications (Sherman et al 2004, Coetzee et al 2005, Doherty et al 2003, Colvin et al 2007, Hsieh et al 2014). The current model of PMTCT care often fails children living with HIV (Hsieh et al 2014). For example, in 2012, early infant diagnosis coverage remained low at 39% in low-income and middle-income countries, with the result that children diagnosed with HIV were only half as likely as adults to access treatment (UNAIDS 2013).

In noting the challenges facing current PMTCT programmes with high rates of loss to follow up (LTFU) of women and low coverage rates of early infant diagnosis, Hsieh et al (2014) urge that PMTCT care must be adapted to respond to the different and complex realities of women, children and families affected by HIV. The well described “PMTCT cascade” refers to a series of service activities at points in time but does not address the reasons why services are used or not used, which the authors hypothesis as being influenced by four contextual realities. These are the *material context* (resources available to a woman or family with HIV), the *relational context* (quality of the woman’s social interactions and relationships), the *psychosocial context* (how a woman may experience HIV diagnosis and treatment emotionally and socially) and lastly the *institutional context* (the availability and quality of local institutions to respond to HIV).

The approach suggested by Hsieh et al (2014) is that the traditional PMTCT cascade, which provides for the clinical needs of the HIV infected pregnant women and their children, but generally does not address the material, symbolic, relational, psychosocial and institutional factors, needs to be expanded to recognize and incorporate each woman’s unique situation and life course. To improve the quality of PMTCT care provided, clinical services need to consider the interaction between clinics, patients, families and community level programmes,

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and engage with how to integrate these various components to provide more client centered care. (Hsieh et al 2014)

An example of more fully integrated care, addressing the psychosocial needs of women in PMTCT programmes is the Mentor Mother (M2M) programme. This is an intervention in which PMTCT clients are linked with trained mentors, who themselves are mothers living with HIV, and provide psychosocial supportive care. Shroufi et al's (2013) mixed methods study of a 3-year M2M programme in Zimbabwe showed that women in the intervention were twice as likely to return for infant testing compared to those who had not enrolled, and when infants were tested at 6 weeks were more likely to have obtained the test result.

Various interventions integrating PMTCT care with community health worker (CHW) programmes have shown positive health outcomes related to HIV viral suppression and to HIV testing rates in infants. A study done in Khayelitsha (Le Roux et al 2013) showed that women with HIV were more likely to obtain key services in the PMTCT cascade, had less birth related complications and their infants had better health outcomes following home visits by CHWs during pregnancy and up to 6 months post delivery, compared to the standard of care.

Within primary health care facilities, interventions which integrate PMTCT care into a family centred care approach have demonstrated improved PMTCT and maternal, newborn and child health outcomes (Tonwe-Gold et al 2009). Integrating and consolidating services for the whole family can address the fault lines in the PMTCT cascade and address the socio-ecological barriers to ongoing care (Tonwe-Gold et al 2009, Betancourt et al 2010). The key elements of such services include providing integrated clinical services for the woman, HIV testing and care of partners and infants, integrated well and sick child care, counseling and

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psychosocial support and referrals for social assistance, amongst others. The comprehensive health needs of the whole family are addressed.

A Ugandan study (Luyirika et al 2013) showed a 50-fold increase of the number of families registered for HIV care, a 40-fold increase of children enrolled for HIV care, with almost complete coverage of cotrimoxazole prophylaxis, following the scale-up of a family-centred approach to HIV care. Task-shifting towards nurse-led clinics with community outreach support enabled rapid scale-up of the programme. This Ugandan experience suggests that family-centred approaches are operationally feasible, produce strong coverage outcomes, and that rapid scale-up can be managed.

In understanding the health seeking behavior of women in PMTCT care, the centrality of the psychosocial dimension of their experiences cannot be underestimated. Programmes which acknowledge this reality and address it through interventions which include integrated care at facilities but also partnerships with supportive peer support organizations and CHW programmes are more likely to yield better health outcomes for woman, their infants and their families. However, despite growing evidence of the acceptability and operational feasibility of these approaches, pilot efforts still predominate and broader scale up and replication of successful programmes has not occurred. What is needed is increased co-ordination between different departments, such as health, community based and social services. The historical silos of HIV programmes need to be overcome, and a paradigm shift regarding the delivery of health services will be needed (Hsieh et al, 2014).

Theoretical Framing for Empirical Research on Integrated PMTCT Programmes

In the preceding section, we focused on literature of an empirical nature, of obvious relevance to integrated PMTCT programs in Southern Africa. In this next section, we turn to

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relevant literature which supports a theoretical frame, on which future empirical work on the implementation of an integrated PMTCT program can be based.

Atun and colleagues published a seminal paper in 2009 proposing a conceptual framework built on theoretical propositions and empirical research, which brings together the critical elements that affect the adoption, diffusion and assimilation of a health intervention such as integration. Atun et al recommend that their conceptual framework be used when undertaking literature reviews, to facilitate analysis of studies and policies on integration, and in reviewing a specific programme or case study. It can also be used to compare integration interventions in different settings. The conceptual framework was developed partly to address the problem that the word ‘integration’ has no commonly accepted definition, making systematic analysis of the relative merits of integration in different contexts complicated. In reality the dichotomy between horizontal and vertical is not rigid and the extent of verticality and integration between programmes varies. Atun et al (2009) note that the presence of both integrated and nonintegrated programmes in many countries suggests benefits to each approach.

Atun defines integration in relation to a set of interacting critical health systems functions that include governance, financing, planning, service delivery, monitoring and evaluation. Interventions such as integration will also be influenced by the following factors: 1) the nature of the problem being addressed, 2) the actual intervention being proposed and how complex it is - which will be affected by how many elements it comprises, the number of “episodes” it requires, as well as the range of users and the stakeholders involved, 3) the adoption system - the key actors and institutions in the system, 4) health system characteristics such as governance, financing, governance, planning, service delivery, M&E and 5) the context or environment (demographic, economic, socio-cultural). Catalysts for

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change could include critical events or technological changes. The interactions between these factors is illustrated in a conceptual framework in which interventions like integration operate in a dynamic interactive context where the interactions are non-linear and complex, and can lead to unpredictable outcomes.

The integration conceptual framework of Atun et al (2009) can be applied to the recommendations of Hsieh et al (2014) regarding providing comprehensive integrated PMTCT care as follows:

The problem: currently many PMTCT programmes have high rates of LTFU of women and low coverage rates of early infant diagnosis. With the increasing push to provide optimal care and with a new international goal being the elimination of mother to child transmission (WHO 2010), there is now a significant global commitment to optimizing PMTCT services.

The intervention: a fully integrated PMTCT care programme, including community based components of care would be in the category which Atun et al would characterize as a “complex” intervention as it “comprises multiple interrelated and interdependent interventions which need to be grouped together and delivered over a period of time, at different levels in the health system by a multidisciplinary group of health care providers to a range of stakeholders” (Atun et al 2009). Atun and co-authors caution that success of such an intervention depends on strong stakeholder involvement.

The adoption system would be what is generally an under-resourced public health system with a high burden of disease and large numbers of clients requiring care. The key actors in this system are the policy makers, managers and different types of health care workers, as well as affected communities, NGO’s and community based organizations. Each of these stakeholders would have different views on the costs, risks and benefits of the intervention, as well as the value of the intervention.

The health system characteristics: these will determine the process of adoption and assimilation of a new intervention such as an integrated PMTCT programme. Integration occurs at different levels of the health system, in relation to critical health system functions which include financing, governance, planning, service delivery, M&E and demand generation.

Finally, the context needs to be considered. The adoption and assimilation of a health intervention, and its sustainability will depend on the interplay of political, demographic, legal, socio-cultural and technological factors, amongst others.

However, Atun et al (2009) also highlight that critical events (which could be political or “catastrophic”) or technological changes (new diagnostic tests or drugs) can provide opportunities for more rapid adoption and assimilation of new interventions into the health system. In some situations, integration will be hindered by factors that influence the health system but may extend beyond it, for example funding constraints.

Theory of Change as Applied to Integration – Practical Implications

While Atun’s model provides a broad conceptual framework for considering how to introduce integration into a programme such as PMTCT, it does not give a clear direction as to how to initiate or implement the process, in a practical way.

There are a variety of approaches which could provide this direction, for example, Greenhalgh et al (2009) have written about the principles of realist evaluation, which is a largely qualitative approach to testing and refining programs by exploring the complex and dynamic interaction among context, mechanism and outcome.

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Theory of Change (ToC) methodology is a broad approach that has been used in both the design and evaluation of programmes. It draws on the traditions of reflective practice for social change. It is a structured way to clarify ideas about change and the impact it will have. It can support innovations in programmes and adapting to change. It is an approach that is inclusive of many perspectives and participants in achieving solutions (James 2011, Taplin and Clark 2012, Vogel 2012).

ToC involves defining long-term goals or outcomes (and the change required) and then mapping backward to identify necessary preconditions to achieve the changes, and explaining why (Vogel 2012, James 2011, Taplin and Clark 2012, Guijt and Retolaza 2012). The process of change is explained by outlining causal linkages in a planned initiative, including shorter-term, intermediate, and longer-term outcomes (Vogel 2012). The identified changes are mapped as an “outcomes pathway”, showing each outcome in logical relationship to the others, as well as chronological flow. The links between outcomes are explained by rationales of why each outcome is thought to be a prerequisite for another. The most strategic interventions to bring about the desired change need to be considered and chosen. Indicators to measure progress on the desired outcomes and assess the performance of the innovation need to be developed and a narrative to explain the summary logic of the innovation is needed (Taplin and Clark 2012).

The outcome may require a change in a group of people, organization, or a context. Outcomes are the building blocks of a ToC process. The most important step in the process is defining the long-term outcome, and if it is clear and compelling will help keep people focused and motivated. All the relevant stakeholders must agree on the long-term outcome. In starting a ToC process, the crucial first step is to elicit a problem statement from the group, which then needs to be addressed.

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The ToC approach is aimed at the “adoption system” of Atun et al’s (2009) framework, while also recognizing the primary importance of the context, as well as how to implement an intervention such as integration. It works with the key actors in this system, namely the policy makers, managers and different types of health care workers, as well as other stakeholders such NGO’s and community based organizations.

Vogel (2012) describes ToC as a process, not a product or outcome. While it is often looked at primarily as a planning methodology, it’s real potential lies in supporting context specific innovation, such as integration. ToC is a way to deal positively with the challenges of complexity. The benefits are greatest if ToC approach used from the beginning of a project before major strategic decisions are made (James 2011).

A central element of ToC approach is the issue of *assumptions*. These need to be discussed (in meetings with a broad range of affected stakeholders) and made explicit. Getting depth and critical thinking on assumptions is at the core of a successful ToC process. Surfacing assumptions means they can be addressed and this can result in innovative ways of addressing challenges.

An assumption is “something that is accepted as true or as certain to happen, without proof” (Oxford dictionary). Assumptions represent the beliefs, values, norms and ideological views, both personal and professional, which will influence how members of a team will respond to a new project or a suggested change. They are deeply held perceptions, and function like “rules of thumb”, but are generally taken for granted. Assumptions need to be checked to see if they are guiding people to behave in ways that are optimal for the context or change that is being considered. Assumptions range from ideas about the context, the cause-effect relationship between interventions, outcomes and context and about the drivers of change.

There can be multiple assumptions at every level and about multiple aspects of a proposed change.

Examining assumptions needs dialogue within a team, comparing ideas through questioning and interaction in order to create a critical thinking approach. It involves activating people's deeply held world views and beliefs, as well as motives for improving the world through their work in the programme or organization. Discussing the things which people care deeply about regarding their work, about the organization they work for and how and why change is being contemplated can bring insight and clarity as well as motivation and a sense of energy.

Blamey and Mackenzie (2007) emphasize that it is not possible to evaluate the impact of changing a programme without understanding the context. An understanding of context is vital in any consideration of the generalizability or the possibility of replicating a programme in another setting. The authors also note that ToC is more time consuming than many other approaches. Substantial time is needed to access and work with a wide range of stakeholders in what can be an iterative and time consuming approach. This is compounded if it is a complex or multi-site intervention.

Complexity and Innovation in Health Care Settings

In order to further understand both the challenge and opportunity of change resulting from the introduction of an innovation such as integration, it is important to consider the literature related to complexity, as applied to health care settings.

Health care organizations can be viewed as complex systems (Plsek and Greenhalgh 2001, Sweeney and Griffiths 2002, Plsek 2003). "Complexity theory" has been described as the opposite of "reductionism" (Sweeney and Griffiths 2002). Reductionism is the underlying assumption of the conventional scientific model which is derived from the notion of

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Newton's "clockwork universe," - a metaphor to explain how big problems can be broken down into smaller and smaller ones, analysed, and solved by rational deduction. This traditional scientific paradigm has strongly influenced both the practice of medicine and the leadership of health care organizations.

To cope with escalating complexity in health care it will be necessary to abandon linear models, accept unpredictability, utilize and respect autonomy and creativity, and respond flexibly to emerging opportunities. Plsek (2003) suggests that much of the current frustration within the health care system around the adoption of innovation is a consequence of the unconscious application of machine-metaphor thinking to what is inherently a complex adaptive system.

Relationships are central to understanding complex systems (Plsek 2003). The behavior of a complex system emerges from the interactions among the agents, and the observable outcomes are often more than merely the sum of the parts. Innovative and surprising ideas can emerge from unpredictable corners of a complex system which encourages diverse relationships among the parties within the system.

Systems are embedded within other systems and the evolution of one system influences and is influenced by that of other systems. This means that the boundaries of a complex system are somewhat arbitrary and "fuzzy". A primary care clinic is a complex system, which is embedded within a district health care system, which is embedded within a provincial health care system, which is embedded within a national health care system, which is embedded within a political system, and so on. At another level, it is also possible to distinguish between formal and informal systems. Ignoring this reality of complex systems is shortsighted. Complexity theory places value and is comfortable with inherent tension

between different interacting systems. Interaction between systems leads to continually emerging, novel behavior.

A traditional way of dealing with challenges in the health care system, based on reductionist thinking, is to try and troubleshoot and fix things - in essence to break down the ambiguity, resolve any paradox, achieve more agreement and certainty, and adopt what may be simplistic approaches. Complexity science suggests that it may be better to try multiple approaches and let direction arise by shifting time and attention gradually towards those approaches that seem to be working best. Kolb's experiential learning model, and the *plan-do-study-act cycle of quality improvement* are examples of approaches that explore new possibilities through experimentation, autonomy, and working at the edge of knowledge and experience (Plsek, 2003).

The application of complexity thinking in healthcare organizations is the hope that the productive interaction of individuals can lead to novel approaches to dealing with problems and challenges. A significant shortcoming of reductionist thinking is the inability to account for surprise, creativity, and new emerging phenomena.

Innovation in Health Care Systems

Plsek (2003) suggests that innovation in health comprises three interrelated processes: 1) The Generation Process involves the creative thinking, which ultimately leads to the conception, development and the initial pilot testing of an innovative idea. Fresh knowledge and new evidence is the seed from which innovation arises. 2) Implementation refers to the processes and challenges associated with implementing a new concept and embedding it into the day-to-day routine within a health care setting. 3) The spread process involves what is done in order to ensure the adoption of the new activities different settings, and possibly throughout the entire health care system

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Innovation takes place within a context that involves the structures, processes, and patterns of the various environments which make up the health care system. The context can be receptive to change and quickly adopt new ideas to meet the challenges experienced, or not. A lack of understanding about the important role of organizational context, or an inability and lack of skill in doing something to make it more receptive, is responsible for much of the frustration with the relatively slow and uneven adoption of innovations in health care (Plsek 2003)

The processes, structures and patterns associated with innovation in some industries are more supportive of creative generation of improvement ideas than are those in health care. Health care organizations would benefit from providing training, and creating research and development (R&D) teams for creative thinking, and facilitating specific innovation projects. These could be aligned with quality improvement efforts, but need to go further.

The implementation of innovative ideas is known to be challenging. The 18th century German philosopher Goethe noted, “To put your ideas into action is the most difficult thing in the world.” One of the consequences of the complexity of health care organizations is their remarkable resilience in the face of pressure, even when the pressure is for positive change. The decision to adopt change must be made by many individuals in a complex system according to personal mental models in which the benefits and risks associated with the change are weighed up. Even when seniors who have power within a hierarchy believe that they can mandate change, individuals “at the coal face” retain their own rights to decide for themselves how they will react.

The Institute for Healthcare Improvement (IHI) researches “improvement methodology” and has been making recommendations on how to support change efforts in health care organizations for 20 years (Berwick 1996, 1998). The IHI rapid-cycle “test-of-change model” helps to implement innovation in a complex system such as health care organizations. It

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allows advocates of innovation to test their ideas under a variety of circumstances, thus making allowance for adaptation and customization. The model includes the possibility that a test will not be successful, but because the test is done on a small scale the risk of failure can be kept to a tolerable level. Most importantly, success on a small scale builds confidence that encourages larger risks as time goes by.

After the generation and implementation of innovative ideas, the next challenge is how to spread them. In complex human systems ideas spread naturally through social contact and networks. Certain individuals in social systems have more influence than others when it came to the spread of ideas, so-called “opinion leaders”. The value of influential opinion leaders has been studied in many settings, and it runs counter to the default positions of “treating everyone as equal and getting everyone’s buy-in”, which is inconsistent with how complex social systems function (Plsek 2003).

Innovation and change take place within a variety of contexts. The importance of context is acknowledged by many authors in health systems research (Atun 2009, Blamey and Mackenzie 2007, Vogel 2012, Guijt and Retolaza 2012). While it is possible to make some general statements about the context for change in health care systems, each situation is different in many important ways.

The context for change is yet another aspect of the complexity associated with innovation in health care. If the goal is the spread of an innovation, it is necessary to describe the innovation, as well as the context in which it was successful. Understanding the influence of context should prevent naïve thinking and expectations that an innovation that was successful in one place will be successful in other places if only “they would just follow the model provided” (Plsek 2003).

A better understanding of the nature of receptive contexts to change is emerging from research into specific attempts at change and the spread of innovation. These include: clear goals, collaboration and teamwork, openness to change or risk, learning from mistakes and strong leadership.

CONCLUSION

There is consensus both internationally (WHO 2010, USAID 2011a, UNAIDS 2013) and in South Africa (SA DoH 2015), that integration in PMTCT programmes is necessary - for many reasons.

The advantages of integrated PMTCT programmes (particularly in Africa) have been documented, as have the challenges. To improve the quality of PMTCT care provided, recommendations have been made regarding the need to go beyond a narrow liner biomedical “PMTCT cascade” approach, and to include a more holistic approach to care (Hseih 2014). Clinical services need to consider the interaction between clinics, patients, families and community level programmes, and engage with how to integrate these various components to provide more client centered care.

Integrated programmes, while not a new idea in Health Systems, are not the norm in PMTCT services, which were initially introduced as vertical programmes (UNAIDS 2013). Therefore, integration in PMTCT has to be implemented as an “innovation”. Health care organizations are complex systems, and this needs to be taken into account when promoting the adoption of innovation in health care systems. Health system researchers should assist in this effort by documenting the experiences of organizations which have been successful in introducing change in order to establish new benchmarks in the health care industry.

Health systems researchers are just beginning to understand the notion of receptive context

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and its relationship to the adoption of innovative change. There is a lack of a consistent methodology and taxonomy to describe the phenomenon of receptive change, and it is not always possible to determine which findings are generalizable. More research is needed, with the goal of creating practical tools and advice for leaders and innovators.

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PART C: JOURNAL ARTICLE MANUSCRIPT

THE IMPLEMENTATION OF AN INTEGRATED PREVENTION OF MOTHER-TO-CHILD TRANSMISSION OF HIV (PMTCT) PROGRAMME AT MCCORD HOSPITAL, DURBAN, SOUTH AFRICA, 2003-2013

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² Instructions for authors in Appendix IX, authors' contribution and information are also excluded. For the purpose of this thesis, the student is the sole and first author of the work.

KEY WORDS

Integration, innovation, theory of change, complexity in health systems, health system, South Africa, prevention of mother-to-child transmission of HIV programmes, PMTCT

KEY MESSAGES

- PMTCT programmes need to be integrated within maternal and child (MCH) services in order to achieve the new WHO goal of eliminating mother to child transmission.
- Integrating programmes within complex adaptive health systems will require innovative approaches to introducing change.
- A better understanding of contexts receptive to change is emerging from research into specific attempts at change and the spread of innovation.
- Strong leadership is crucial to lead and sustain efforts to implement innovations in health systems.

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- The women, their partners and infants who received care in the McCord PMTCT programme

ABSTRACT

The international call for the elimination of MTCT will be a challenge to meet, given the complexity of health care systems in general and in particular in LMICs such as South Africa. Integrating PMTCT care into routine MCH services has been recommended by various international institutions and authors as a way to optimize PMTCT care, and while integration is not a new health system concept, the reality is that it is difficult to do in practice, given that it was introduced as a vertical programme. It will require an innovative approach to managing change in complex adaptive systems. Lessons about implementing health system changes such as providing integrated PMTCT care can be learned from programmes which have done so successfully. McCord Hospital established a longitudinal integrated comprehensive PMTCT programme which provided holistic care from the time pregnant women presented to the antenatal clinic, segueing into combined mother-child follow up care post delivery until the infant was 18 months old. Using Case Study methodology, the process of developing the fully integrated longitudinal clinic at McCord Hospital is described, and reflections on the experience of providing integrated care for the 5 years the “Mamanengane Clinic” was operational are captured through qualitative interviews with the staff. Theory of change approaches are used to understand the processes which enabled the development and implementation of this exceptional PMTCT programme. Recommendations regarding innovation and change within complex systems are suggested, emphasizing the need to understand contexts which are receptive to change, and the importance of leadership in managing change.

INTRODUCTION

The latest international goal for prevention of mother-to-child transmission of HIV (PMTCT) programmes is the *elimination* of mother-to-child transmission (MTCT) (WHO 2010). This has resulted in a significant renewed global commitment to optimizing PMTCT services.

The World Health Organization (WHO 2010) states that successful elimination of MTCT will require a high level of commitment, a new way of organizing health systems, and new ways of working to support PMTCT at the global, regional and country levels. For this to happen, it will be critical to have strong leadership at all levels, political and other stakeholder buy-in as well as increased and sustained financial support (WHO 2010, UNAIDS 2013).

It has been argued that PMTCT programmes are a cost effective intervention that provide a measureable reduction in HIV transmission (Killam et al 2010). Studies assessing the benefits of integration in PMTCT programmes in Africa reported predominantly positive findings, including significantly increasing the enrolment of HIV infected women into ART care (Tsague et al 2010, Killam et al 2010), as well as better follow up of HIV-exposed infants (Odero Ong'ech 2012).

The achievement of Millennium Development Goals (MDG) 4 and 5 would be directly impacted by providing good quality PMTCT care. However, the Countdown Coverage Working Group (CCWG) report on achieving the MDG's, highlighted that opportunities to improve care through integrated delivery of interventions have largely been missed (CCWG 2008).

The vision for integration calls for inclusion of PMTCT interventions within the full continuum of Maternal and Child Health (MCH) services, as well as sexual and reproductive

health programmes (Sripipatana et al 2007, Baek and Rutenberg 2010, USAID 2011a, UNAIDS 2013), because of the high burden and risk of HIV infection among pregnant women in Africa.

While the international literature recommends that integrating PMTCT care will have many benefits, the reality that it is a challenge to implement the integrated PMTCT services, is also noted. It is widely acknowledged that there is a need for more research into integration, in particular implementation practice (see Abrams et al 2007, Atun et al 2009, Church and Mayhew 2009, Kennedy et al 2010, USAID 2011, Dudley and Garner 2011, Tudor Car et al 2011, Anand 2012, Lindegren et al 2102).

The South African Department of Health (SA DoH) 2015 National Consolidated HIV Guidelines (SA DoH 2015) call for the integration of PMTCT into the existing MCH services, as recommended by international agencies. Horwood et al (2010) found that a high coverage of PMTCT interventions during pregnancy and delivery, but follow-up of mothers and infants was poor, confirming the findings of an earlier South African study (Jones et al 2005). Horwood et al noted that poor integration of PMTCT services into routine care, lack of clarity about health worker roles and poor record keeping created barriers to accessing services post delivery.

The SA DoH policy plans are therefore currently more ‘aspirational recommendations’, given the challenges facing implementation, as well as the absence of guidelines for policy implementation. In his 2011 budget speech, the South African Minister of Health, Dr Motsoaledi, stated that “the public health care system is bedevilled by very poor management leading to poor quality of care” (Doherty and Gilson 2011). Plsek (2003) notes that complexity in health care organizations can make them remarkably resistant to change. The implementation of a successful intervention such as one that integrates PMTCT care into

MCH services, will need an active change management process, and decisive leadership to ensure that change happens, and to overcome resistance (Doherty and Gilson 2011).

In South Africa there has been limited operational or implementation research on PMTCT programmes which have been integrated into broader services, particularly the follow up of mother-infant pairs (Chetty et al 2012, Jones et al 2005). The integrated PMTCT service experience at McCord Hospital in Durban presented here therefore provides a useful case for drawing lessons from a historical implementation experience. Retrospective work is critically important so that key implementation lessons are not lost, and can be carried forward into multiple emerging integrative practices in South Africa and in other low and middle income country (LMIC) settings.

METHODS

Case study methodology was used in this retrospective study of the McCord Hospital model of integrated care because it allows for consideration of how and why a phenomenon is influenced by the context within which it is situated (Baxter and Jack 2008).

The case is the history of the development and the implementation of the integrated PMTCT service from 2003 to 2013.

The goal was to assess what lessons could be drawn from the McCord integration experience that might have value in addressing challenges to providing more integrated PMTCT care in other settings. Case study research according to Yin (1984) is “an empirical investigation into a contemporary phenomenon within real life, using multiple sources of data”. In this study we focused on a single case situated in a specific social and physical setting, with the purpose being to demonstrate the multiple contextual factors influencing the working of health system (Gilson 2011). Case studies are useful to identify the various influences, to examine inter-

relationships (complex causality) and to generate ‘theory’ which can be further tested through future work (Baxter and Jack 2008).

The integrated longitudinal care model of the McCord PMTCT programme is an ‘exceptional’ example of a PMTCT programme in South Africa, because there are very few examples of PMTCT services which provide 18 month post natal care, despite recommendations (SA DoH 2015) that PMTCT care should be integrated into routine MCH care. Exceptional cases are valuable as they may provide new insight into a problem or new leads for further inquiry (Baxter and Jack 2008).

This is a sub-study, drawing from a larger research project on the McCord Hospital PMTCT programme. Three evaluations of the McCord PMTCT programme have been published (Geddes et al 2008 and 2011, Chetty et al 2012). A prospective study to evaluate the clinical outcomes of the programme was begun in January 2010 (data collection was completed in 2012 and analysis is in process). In addition to the clinical outcomes, in order to assess the operational components of the programme, seven in-depth interviews with the staff (the manager, doctor and nurse clinicians, counselors and the monitoring and evaluation (M&E) officer) were done to assess their views and perceptions regarding the implementation of the programme. Each interview lasted approximately one hour.

This case study was conducted in 2014 and 2015, drawing from multiple information sources, including a primary analysis of the seven staff interviews conducted in 2012, primary documentation (including treatment protocols and reports to funders), the existing evaluations of the McCord PMTCT experience (Geddes et al 2008 and 2011, Chetty et al 2012), as well as observation by the primary author (JG). The observations were conducted as part of regular work: during team meetings, in discussions with individuals and in doing audits of clinical files. The purpose was to understand the daily practices, staff routines, flow of

patients through the clinic, clinical care provided and what problems were arising and how they were being addressed.

The primary author was the overall manager of the McCord Hospital HIV-care Programme (including PMTCT) from 2003 to 2010. This case draws substantively on her observation, while maintaining rigor through reflective practice. Validity and triangulation of findings was done by checking with the other PMTCT researchers at McCord hospital, as well as study participants, such as the PMTCT programme manager.

The McCord Hospital Research Ethics committee (see Appendix 4) gave permission in 2012 to conduct the interviews with PMTCT programme staff, and the UCT ethics committee gave permission in 2014 (see Appendix 5) for these interviews to be analyzed, as part of this case study write up.

In the article that follows, the history of the development of the integrated PMTCT service implementation (the case) is presented, followed by the reflections of the staff on their experiences of implementation.

RESULTS

The Case: The McCord Hospital integrated PMTCT programme, 2003-2013

The retrospective case being presented is a description of the development and implementation of a fully integrated longitudinal PMTCT service at McCord Hospital, which was operational for a five-year period (2008-2013).

The setting: McCord Hospital

McCord Hospital was a state-aided general hospital in Durban, South Africa, with a history of “attracting visionaries and nurturing leaders” (Giddy 2005). The patient population who

accessed care at the hospital was predominantly lower-middle-income, medically uninsured, and black South African. They could afford (or who had families who could assist) to make a financial contribution to their health care and were not the poorest members of the community. The hospital received a partial government subsidy, and the remainder of the funding came from patient fees and a variety of donors.

The hospital received PEPFAR funding in 2004 to scale up the treatment of all HIV infected people coming for care, and used this funding to establish a comprehensive HIV programme comprising a number of components including pre-antiretroviral treatment (ART) care, ART for adults, ART for children, ART initiated in very ill hospital in-patients, PMTCT care, and an HIV research programme.

HIV infected patients (including women in the PMTCT programme) paid a monthly user fee of R160 (~\$US24) for all HIV related care (Giddy 2005, Geddes et al 2011).

The PMTCT component of the HIV programme received dedicated funding, as a discreet component of the overall HIV programme funding from PEPFAR. The PMTCT programme had specific targets and reporting requirements, which constituted a specific section of the overall HIV programme, but were included in the general PEPFAR report and budget. There was no competition for HIV related resources between different services at the hospital.

Over 10 000 patients had been initiated on ART when the comprehensive HIV programme (including PMTCT care) at McCord Hospital was closed down in 2013 because PEPFAR funding was withdrawn and the KwaZulu Natal Department of Health did not take over the support of the hospital (Cloete et al 2014).

The development of the PMTCT programme

PMTCT care at McCord hospital began as a vertical programme, early in the South African HIV epidemic in 1995, with HIV testing initially provided as a result of a research project needing to identify pregnant women with HIV for a study to evaluate the efficacy of Vitamin A to prevent MTCT (Coutstoudis et al 1999). Vitamin A was not found to be effective for PMTCT, but as a result of the study, a nascent PMTCT programme was established at the hospital.

A dedicated general HIV clinic (“Sinikthemba”³) was also established within the hospital in 1996, which initially provided limited primary medical care, focusing more on psycho-social support and income generating projects (Giddy 2005). The clinic started to provide ART in 1999, as part of a clinical trial by Quintiles, a pharmaceutical company, as well as to patients who could afford the cost of ART at commercial pharmacy rates. Due to the high cost of ART, by early 2003 only around 100 patients were receiving ART. In early 2003 a strategic decision to expand the small HIV care programme was made by the Hospital Board. To manage the scale up of a more clinical HIV programme, a Family Physician (JG) was appointed as the overall HIV programme manager, to replace a social worker, with the directive to seek external funding and provide leadership to fulfill the strategic goal of expansion.

PMTCT was immediately targeted as a starting point for improving the general quality of HIV care at the hospital. In 2003 PMTCT care options in the public sector were very limited: following a Supreme Court decision, the Minister of Health agreed to provide single dose nevirapine to pregnant women in labour and to the infant (Burton et al 2015). The McCord HIV programme staff were aware that there were better evidence-based PMTCT options, and

³ Sinikithemba means “We give Hope” in isiZulu

having more autonomy and flexibility wanted to offer better care to pregnant women (Giddy 2005).

A doctor was appointed as the PMTCT programme manager, after funding from the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) was received to improve the PMTCT programme in 2003. Integrating PMTCT care within routine antenatal care was the first challenge which the growing team of counselors and nurses addressed, with the goal of providing a more optimal patient experience. The March 2005 report by a technical assistant to EGPAF noted that the PMTCT programme “makes great efforts to ensure *seamless* services between ANC/PMTCT and treatment” (Preble 2005).

From 2004, additional funding provided by PEPFAR was used as a catalyst to provide evidence based better PMTCT care options (McCord Hospital 2005, Geddes et al 2008). Geddes et al published two evaluations (2008 and 2011) of the funded PMTCT programme covering the period 2004 – 2007. Both evaluations showed overall good clinical outcomes, including a MTCT rate of 2.8% at 6 weeks post delivery, which they noted to be “outcomes that compare favourably with those in the developed world” (Geddes et al, 2008) . The national estimates of MTCT transmission rates in the public sector prior to 2010 ranged between 8 – 22% (Goga et al 2012).

The McCord programme outcomes were attributed to the use of evidence-based flexible approaches to PMTCT care (the use of CD4 counts and viral loads to tailor treatment, which included ART). However, it was noted (Geddes et al 2011) that longer-term follow-up of mothers’ and babies’ health presented a challenge, given that six months post delivery only 21% women were receiving follow-up care at the adult HIV clinic. The following recommendation was therefore made: “the importance of longer term follow-up must be emphasized and successful strategies to link women to ongoing care are crucial to sustain the

gains of PMTCT programmes” (Geddes et al 2011). The HIV programme staff had reported concerns about the long term follow up of women post delivery to the funders (McCord Hospital 2006a), and proposed a strategy to address this, in the form of an ‘*integrated* post-natal mother-infant follow up clinic’.

Other factors that were noted to have contributed to the success of the PMTCT programme up to that point included “a unified vision, good leadership, support from senior management, adequate resources, use of evidence-based approaches, development of protocols and systems, a learning organization approach, a multidisciplinary team with committed staff and relative autonomy” (Geddes et al 2008). The PMTCT staff worked closely with the general HIV programme staff as well as the other relevant hospital departments.

The antenatal integration which had been implemented in the PMTCT programme over an 18 month period (2004 – 2005) was described as follows: “Integration is frequently mentioned as a strategy to improve care and reduce stigma. At McCord integration took place on two levels. PMTCT patients were integrated into general antenatal care, and staff participated in both HIV and non-HIV care. This allowed women a greater degree of anonymity” (Geddes et al 2008).

Programme challenges were also noted, in particular the ongoing need for well-trained staff, adequate infrastructure and space for clinical care so that confidential issues could be discussed in privacy. It was also observed that a similar programme might not be appropriate in settings with limited expert support and a high staff turnover (Geddes et al 2008).

A decision was then made in 2006 to apply to PEPFAR (McCord Hospital 2006b) for additional funding to establish a dedicated longitudinal follow up clinic called

‘Mamanengane’⁴ for women and their infants up to 18 months post delivery, in order to improve post natal retention in care.

Planning for and implementing the Mamanengane (Mother-Child) integrated clinic

The establishment of the new Mamanengane post natal clinic represented a vision of fully integrated longitudinal PMTCT care. This involved the development of a new strategic plan (developed by a small team), funding (provided by PEPFAR), physical infrastructure (mobile units) and equipment, developing appropriate patient records for mothers and children, clinical guidelines and standard operating procedures (PMTCT protocols for 2008, 2009 & 2010), customizing the HIV programme electronic patient record, and recruiting and training appropriate staff.

The planning was done over a period of 18 months, and the integrated Mamanengane clinic started enrolling mother-child pairs in May 2008.

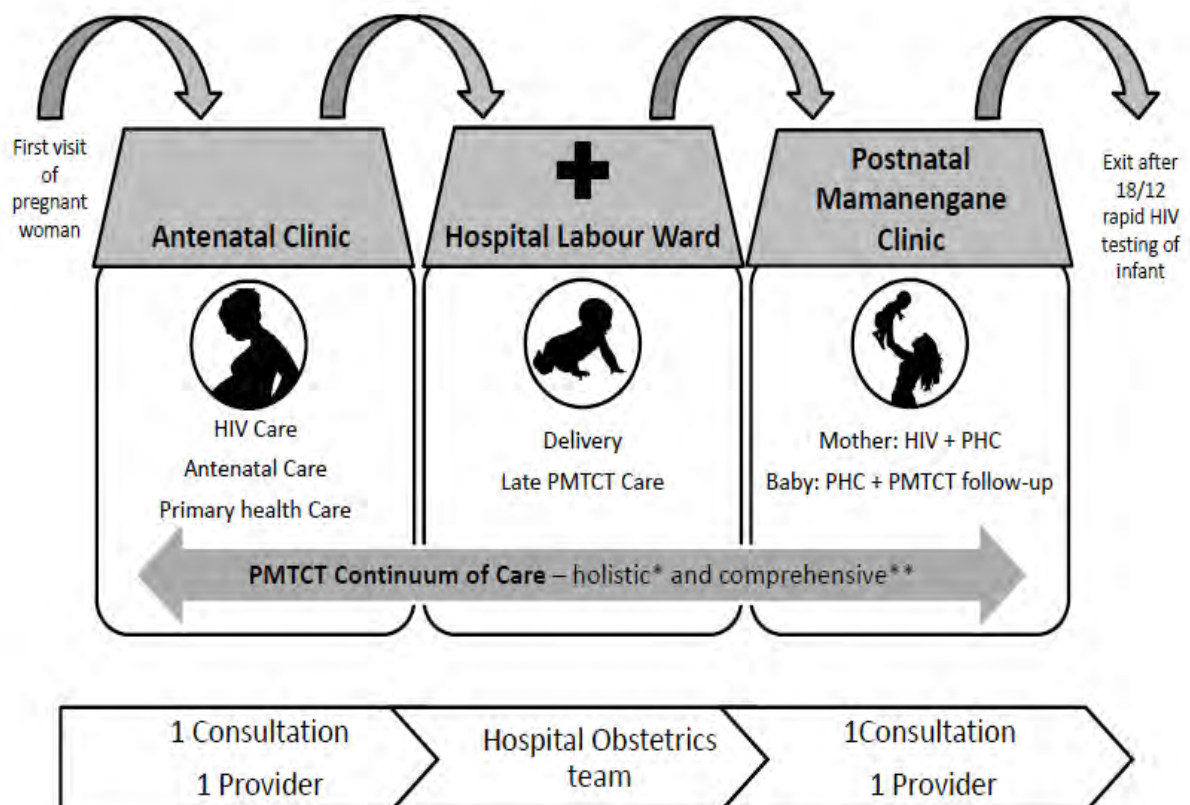
A significant strategic decision was to employ a non-clinician (with a long association with the HIV programme as a researcher), as the PMTCT programme manager. This was in response to the identified challenge of finding suitable leadership of the PMTCT programme. The managers prior to 2008 had all been young clinicians (nurses or doctors), who provided good clinical oversight, but did not have ‘systems’ management experience, and had struggled with finding a balance between clinical responsibilities and management. In addition, they were mobile, most remaining in the post for one year only. This frequent turnover of leadership created instability in the programme (JG observation) and made long term strategic planning and innovation difficult. The team leader appointed in 2008 was not a clinician, but worked closely with the clinicians and was able to effectively co-ordinate both the clinical programme and the related research programme. The primary author (JG)

⁴ “Mamanengane” means Mother and Child in isiZulu.

observed that it was the mature perspective, willingness to learn and excellent interpersonal and communication skills, which made this team leader effective.

The model of care was that the same team of midwives (trained to provide general HIV care, as well as maternity and infant care), with a doctor clinician as a mentor and supervisor, provided integrated comprehensive care to pregnant women 3 days a week, and on the other 2 days the Mamanengane clinic provided post natal HIV care to women, and comprehensive care of the infants, including wellness care (growth monitoring, immunizations, Vitamin A) as well as primary care of minor ailments, with referrals to doctors for more complicated problems.

Figure 1: Diagrammatic Representation of the McCord PMTCT Programme (Source: J. Giddy)



* Holistic = Psychosocial Counselling + support (Partners and children included)

** Comprehensive = ANC, HIV, TB, Reproductive health, cervical screening, PHC

Counselors did pre- and post-test HIV counseling, ART preparation counseling, ongoing counseling to support adherence as well as other psycho-social issues such as discordancy, and partner problems. An M&E officer provided data support and the tracking of various aspects of care, for reports to funders. The clinic team met weekly to discuss clinical problems, do chart reviews to check quality of care, and discuss operational issues.

In 2012, when the PMTCT programme was facing closure, the staff were all interviewed in order to document their experiences of providing integrated care.

In order to fully understand the impact of the integrated service, it would have been ideal to interview some of the women who received PMTCT care at McCord Hospital, as well as their partners. However, by the time this case study was being written, the McCord programme had been closed, so it was not possible.

Reflections of the PMTCT Staff on Providing Fully Integrated Longitudinal PMTCT Care

The findings of the qualitative analysis of the staff interviews provide an insight into the case of the implementation of an integrated PMTCT service. The interviews reflected the perceptions of the staff regarding the components of an integrated PMTCT programme, what the advantages, challenges and successes were, and their ideas regarding the replicability.

Integrated care was not easy to define for some of the participants, and varied according to level of staff, with the more senior staff and clinicians (who had been part of the strategic planning of the Mamanengane clinic) being able to articulate a definition more easily. *“It’s quite a broad concept because it can mean quite a few things. It’s about not wanting to duplicate systems... it’s trying to provide care under the same roof... trying to provide a mix*

of services in the same facility, to avoid people to have to seek care at multiple points”
(Programme Manager 2012)

However, although not being able to articulate a “neat” definition, staff at all levels had a clear idea of what integration entailed in practice and they could give reasons for why integration was necessary, and could describe characteristics of what integrated care should look like, with the following included as comprising the type of care provided in the programme: PMTCT and antenatal care combined, holistic care, comprehensive care, *“including clinical care, ARV’s, labs, baby care, TB, reproductive health”* (nurse clinician 2012). The related notion of the PMTCT “continuum of care” was articulated as: *“where you see the moms from the time they come to our antenatal clinic for their antenatal visit, they deliver their babies and then you continue care from there, until the babies are 18 months and also looking after the mother’s well-being”* (nurse clinician 2012).

The main explanations of how integrated care was provided, was a variation on the theme of care in one consultation by one provider: *“patients don’t have to go to different clinics like going to TB clinic because now they got TB. Also STI clinic because they got some sexually transmitted infection, everything can be cared for at one stop”* (nurse clinician 2012).

The perception of the staff was that it was the integrated nature of the service that resulted in the successful programme outcomes, as measured by a MTCT rate of less than 1%: *“we have a very low transmission because of Mamanengane.... a mother here last week was in tears because we gave her a negative result...you just give mothers joy so that says the service, it definitely works. It’s successful”* (nurse clinician 2012).

The staff generally found more advantages to integrated care than disadvantages. Perceived advantages included: time saved for the mother, improving adherence and retention in care, improving the quality of care, the value of tracking post natal care, dealing with issues which

‘fall between the cracks’ (infant feeding, contraception, cervical screening), keeping mother and baby together and providing continuity of care over 18 months: *“You must keep them together as a team for 18 months. I think it very vital to the baby’s well-being and the mum’s well-being”* (counsellor 2012).

The value of holistic and family care, including partner involvement was also mentioned by several staff, who indicated that this was more satisfying for both patients as well as providers, and led to a greater depth of relationships. The involvement of male partners was also viewed as a sign of success: *“Sometimes the men came on their own to bring the baby for the immunizations. That for me was the greatest triumph to see them actually engaging in the wellness care of their infants”* (nurse clinician 2012).

An awareness of the costs and challenges of providing integrated care was also shown, in particular the challenges of implementing and managing a complex system. *“It’s really complex to manage. It needs highly trained staff who are able to be very versatile”* (Programme Manager 2012). Complexity was articulated in multiple ways including the clinical complexity of providing integrated care. Nurses need to be well-trained to provide ART, reproductive health services, TB care and the care of infants. The ongoing training of the nursing staff was a challenge that was prioritized. Training was provided in various ways: through “in service training” by the doctor clinician (who gave feedback on individual patients), through case discussions in the team meetings and in the weekly continuing professional development HIV programme meetings (for all the HIV clinical staff).

It was also noted that it was complex to manage the costs of integrated services: *“We did charge for services and that was a whole other level of complication because women and children present in different permutations. We had a whole bunch of exceptions to that protocol so that was a logistical nightmare”* (Programme Manager 2012).

Providing integrated care was time-consuming for the staff, with consultations taking a minimum of 30 minutes, which sometimes resulted in long queues and disgruntled patients. The increased workload was experienced to be stressful: *“because nurses are now seeing babies and a mum, instead of just seeing one patient, it’s quite taxing on you physically and you’ll likely burn out because you’ve got a lot of patients. I mean sometimes we had about 70 patients, and it was just mainly the two of us”* (nurse clinician 2012).

When asked about the reasons for the perceived success of the integrated programme, strong leadership to co-ordinate the activities of the team was noted as important: *“it’s better to have one person who is in charge...if there is no one who is in charge, people would be doing as they please because we’re human and we need to have a manager in the program, who will oversee if everything has been done and has been done correctly”* (M&E Officer).

In addition to the leadership, tribute was also paid to the passion of the staff and team work: *“the staff are particularly dedicated, particularly passionate...key, was the lack of hierarchy. So you don’t have the doctor at the top of the chain and the counsellor at the bottom of the chain. Everyone was respected for their particular skill set and they worked together in a cohesive team but again it goes to strong coordination, pulling people in line, allocating, people having very clear duties, very clear responsibilities and a very clear understanding of how they meshed with one another with a single person coordinating it”* (PMTCT doctor 2012)

The staff members also referred to the weekly meetings where chart reviews were done, and clinical care and operational issues discussed, as well as the policies and protocols developed to guide the programme, which was linked to maintaining a good standard of care. The confidence expressed in the integration process were attributed to adequate time taken to establish systems, orientate staff, team work and funding.

When asked about recommendations for replicating a similar service in another setting the starting point was noted to be the need to have a shared vision for integrated care as well as the necessary resources. As noted above, good management and leadership was a key factor, mentioned a number of times by participants. Suitable staff, who had regular meetings and worked well as a team was essential. The staff need ongoing training, support and mentoring backed up by protocols and standard operating procedures which would assist with issues like a good patient flow system. An electronic patient record for tracking patients would support a good M&E system, and laboratory and pharmacy support were also needed. The need for the buy in of relevant stakeholders, funding, and the need to take into account the context were points raised by more senior staff. Participants cautioned that the McCord PMTCT programme would be difficult to replicate elsewhere. One participant suggested that it might be easier to start a new integrated PMTCT programme rather than attempting to change an existing one.

DISCUSSION

What is Integration and Why do it?

It is not surprising that the health workers found it difficult to articulate a clear definition of integration, considering that integration was never presented as a formulated concept at McCords, but rather emerged organically as the best way to provide optimal patient centred care. However, the senior PMTCT staff did have a vision for what integrated care consisted of and were able to communicate that in a way that the rest of the team clearly understood the components of an integrated programme, and were able to explain these to the interviewer.

If staff members understood integration in significantly different ways, or did not understand it at all, it would impact on how they bought into the goals of the programme, and how they

coped with the costs and challenges of providing integrated care. A key lesson from this case was that while it is currently the default mode of health care workers to operate in a siloed or vertical programmatic way, what was particularly successful here was the gradual development of a coherent shared broad vision of integration (see below for further discussion on this issue).

The finding of both advantages and challenges to providing integrated care is similar to what has been found in the literature (Newell 2004, Abrams 2007, Winestone et al 2012, Vo et al 2012). Contexts differ and this coupled with factors such as level of skills of health care workers, will affect the implementation of integration (USAID 2011b). The McCord's staff listed a number of advantages to integrated care, including continuity of holistic, comprehensive care, which they linked to better adherence and retention. This, coupled with the time saved for the mothers, was perceived as providing improved quality of care. Psychosocial and family care, including male partner involvement was also valued. Abrams et al (2007) noted that PMTCT services can act as gateways to family-based HIV care. Male partner involvement (MPI) has been identified as a priority intervention in PMTCT, but rates of MPI remain low worldwide (Brittain et al 2015), so this was a significant achievement.

The challenges of integration have been very well documented (Scripitapata 2007, Atun et al 2009, Tudor Car et al 2011, USAID 2011a, Smart 2012), and include some of those noted by the McCord's staff such as the costs, the need for well trained staff to provide comprehensive care, and the work load implications including the risks of burnout. McCord staff noted that managing the complexity, was time consuming and required "strong management". While Smart (2012) notes that sometimes the motivation to integrate is externally driven, in this case, it was an internal drive, but supported and encouraged by the funder.

In considering the reasons for the perceived success in implementing this integrated PMTCT programme (and the implications for replicability), the importance of vision and long term planning are the starting points. The support of the hospital management was crucial (JG observation), as a dedicated team embarked on a structured process of planning for change.

Theory of Change Process as a Model for how to Implement Integration

In retrospect, the McCords team could be said to have embarked on a Theory of Change (ToC) process – although it was never explicitly termed as such. Built around a goal of change, a ToC process includes a series of connected building blocks, linked in a causal pathway, required to bring about change (Vogel 2012). It requires participants to be clear on long-term goals, identify measurable indicators of success, and formulate actions to achieve goals. A ToC process provides a roadmap to get you from here to there. If it is well done, the roadmap can be read by others and indicate how to chart the course (Vogel 2012).

The McCord's team realized in 2005 that they needed to improve retention in care (Geddes et al 2008), so this was the long term goal that guided the planning. Numerous planning meetings were held to work out how to develop a post natal follow up clinic for mother-child pairs. Accountability to and support from the funder kept the focus on ensuring the plan was implemented.

The staff were aware by the end of 2012 that it would be difficult to replicate this kind of service elsewhere, because of the complexity involved in this kind of intervention. They referred to the PMTCT programme as “complex” and they realized that it represented some kind of “ideal”.

Doherty and Gilson (2011) have described the steps required in a change process, and advise starting with identifying the ‘implementation gap’, which can be the inverse expression of a

vision statement. In this case the gap was the lack of long term post natal follow up services. The next step is to be clear about the vision and develop a task team that has the mandate to implement changes over time. To improve retention in care, a PMTCT programme manager was employed who built an implementation team that shared the vision of providing integrated post natal care.

The staff were carefully selected and their technical competence developed through ongoing in- service training and mentoring. They had a clear sense of purpose, their roles were well differentiated and each staff member had a defined set of tasks, guided by the clinical protocols and SOP's, as recommended by Doherty and Gilson (2011). In implementing a complex change, Doherty and Gilson (2011) recommend listening carefully to what staff members say as they have insight into operational issues.

Understanding Complexity and the Implementation of Innovation

In discussing the replicability of the McCord programme, staff members cautioned the need to recognize the complexity. Health care organizations have been described as complex systems (Plsek and Greenhalgh 2001, Plsek 2003, Doherty and Gilson 2011). A complex adaptive system consists of a collection of individual agents with freedom to act in ways that are unpredictable. Relationships are central to understanding complex systems because the behavior of a complex system emerges from the interactions among the agents. "Generative relationships," are interactions in complex systems which produce valuable, new, and unpredictable capabilities that are not inherent in any of the parts acting alone. Innovative and surprising ideas can emerge from unpredictable corners of a complex system (Plsek 2003).

Based on the primary author's experience and perception (JG) the relationships within the McCord PMTCT team were a significant part of the reason for the success of the programme. The weekly PMTCT team meetings were non- hierarchical and inclusive, they improved

communication and the integration of the multidisciplinary team, and helped build trust. They were a forum for regular feedback and an opportunity to resolve tensions or misunderstandings. They ensured buy-in from staff implementing the intervention and helped with developing shared understanding and overcoming challenges, and contributed to the ongoing development of the programme (JG observation).

The Importance of Leadership in Innovation Within a Complex System

Leadership and management are vital elements of every health system – they represent the core of what the WHO has termed ‘health system governance.’ Doherty and Gilson (2011) recommend that leadership be prioritized as a key element of health systems strengthening, and training for leadership should be provided at all levels.

While the participants did not mention the word leadership specifically, it is clear that they were aware that this was a key reason for the success of the programme. Leadership should promote team work to ensure that the programme functions optimally, and the staff were also aware of the value of the team.

Doherty (2014) examines the issue of “clinical leadership”, meaning leaders or managers who are clinicians, such as doctors or nurses. Clinical leaders usually continue some part-time clinical work, keeping them in touch with patient care, and helping them to understand what is needed to improve the quality of care. However, they have the challenge of balancing clinical activities with management. Doherty raises several pertinent questions regarding clinical leaders, including whether clinicians have the skills to be leaders and ‘systems’ managers. The PMTCT manager employed in 2008 was a non clinician, who provided more effective leadership than the previous clinical leaders, because of her different skill set (including knowledge of a systems approach), as well as being able to give her undivided attention to management.

Given the complexity of the programme, with many components to manage, strong leadership was crucial to ensuring that the integrated PMTCT service functioned effectively.

The Influence of Context in Innovation Implementation

The importance of context in complex systems has been highlighted by Plsek (2003). To ensure the spread of an innovation (its generalizability), then it is not sufficient to describe only the innovation, but also the nature of the context in which it was successful.

The McCord's institutional context was supportive of innovation, led by a CEO who was a visionary and inspirational leader who intentionally cultivated leadership at the hospital. These qualities were recognized when she was awarded the South African Businesswoman's Association⁵ Social Entrepreneur award in 2009 for, amongst other qualifications for the award, her leadership qualities and using unique and innovative approaches to social problem solving (Global Ministries 2009).

The hospital being "state aided" functioned autonomously - staff members who showed initiative were valued and innovative ideas were actively encouraged (opinion of the primary author JG). There was an organizational culture of openness and receptiveness to innovation, as evidenced by the establishment of the HIV programme in the mid 1990's, long before HIV care received dedicated attention in Durban hospitals. Linking with research projects and other partner organizations laid the ground for applications to various funders, which culminated in attracting significant PEPFAR funding in 2004. This provided resources for the rapid scale up of all the HIV programmes including the PMTCT services.

⁵ The Businesswoman's Association is the largest and most prominent association of business and professional women in South Africa and the voice of women in business.

Limitations of the Study

This study does not engage in-depth with the broader social context within which the programme was implemented, although the patient population is briefly described, and the setting of the hospital is a large city in South Africa. Understanding a system's complexity is not only affected by the internal factors of the system (institutional context), but also by external factors. These can affect how services are rendered, received and utilized and influence health seeking behaviour. A description of this broader social context was beyond the scope of this study and it is acknowledged that this may limit the generalizability of the study, and the relevance for other settings. Also, while it would have added value to the study to interview the woman who used the service and their partners, this was not practically possible and is a limitation.

CONCLUSION

It is argued that PMTCT services need to engage strategically with the issue of integration if they are to achieve the aspirational goal of eliminating MTCT. Integration is itself an aspirational goal in most health care systems in LMICs, including South Africa. Programmes which have successfully been integrated into comprehensive care systems can provide valuable lessons for replicability.

McCord hospital was able to implement an integrated longitudinal PMTCT service because of an identified need, external funding and a context which was supportive of innovation. Leadership, a clear vision, focused planning, resources to hire good staff and develop SOP's and electronic patient records, coupled with teamwork were contextual factors which contributed to establishing a solid foundation for the integrated Mamanengane clinic.

To integrate PMTCT services within MCH services, as the SA DoH has recommended (SA DoH 2015), needs to be accompanied by specific integration implementation guidelines and training. It cannot be assumed that service providers will intuitively know how to implement this kind of significant change.

Atun et al (2009) proposed a conceptual framework linking the critical elements affecting the adoption of a health intervention such as integration. These are the nature of the problem being addressed, the intervention being proposed and how complex it is, the adoption system (key actors and institutions), health system characteristics such as governance, financing, service delivery, M&E and lastly the context. Recognizing that health systems are complex (Plsek 2003), and that introducing innovations such as integrated programmes, is challenging, health system managers need to consider carefully how to manage change. This starts with a clear understanding of why the change is needed (the nature of the problem, in Atun et al's framework), having a vision for the change (the intervention being considered), and then planning strategically how to achieve the goals, which can be done using a ToC approach.

A better understanding of contexts receptive to change is emerging from research into specific attempts at change and the spread of innovation (Plsek 2003). These include collaboration and teamwork, openness to change or risk in the adoption system and learning from mistakes. Plsek recommends establishing health care Research and Development departments in the health care system and the need for structural support such as providing protected time for staff at all levels to network, explore ideas, and test new ways of working will facilitate greater spread of innovative ideas. And finally, aim to normalize change in health care organizations, to establish a pervasive 'habit for change'. All of these recommendations resonate strongly with what was found in this case study.

Most importantly, strong leadership is crucial to lead and sustain efforts to implement innovations such as providing a fully integrated comprehensive longitudinal PMTCT service.

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APPENDICES

APPENDIX 1: SEMI-STRUCTURED INTERVIEW GUIDE

This consent form was utilized in the primary study approved by the McCords Research Ethics Committee (see below). It is presented here for information only – since these interviews have already been conducted, and this study will consist of a secondary analysis of these transcripts (inter alia).

Integration of PMTCT Care at McCord Hospital PMTCT Programme	
Unique Study ID: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Interviewer Initials: <input type="text"/> <input type="text"/> <input type="text"/>
Date of interview: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/>	
DD	MMM YYYY
Q1. Sex	1 <input type="radio"/> male 2 <input type="radio"/> female
Q2. What is your professional role at work	1 <input type="radio"/> midwife 2 <input type="radio"/> NIMART trained nurse 3 <input type="radio"/> manager 4 <input type="radio"/> Counsellor

Good morning.

If the participant has agreed to the interview being audio recorded:

I am now going to turn the audio recorder on. I will not use your name during this interview.

Are you ready for me to turn the audio recorder on?

The topic I want to talk to you about relates to integrated services

1. Can you please tell me a bit about the activities that you are engaged in, in relation to PMTCT services?

2. What do you understand by the concept of integrated health programmes?
3. Could you describe the type of care which is currently offered to PMTCT clients at McCords and comment on whether you think it is integrated or not.
4. In your opinion, what are the advantages of an integrated health service?
5. In your opinion, what are the disadvantages or challenges of an integrated service?
6. Could you tell me if you view PMTCT care as a key service in maternal, child and women's health services? (Probe for reasons based on answer)
7. Please can you share your thoughts on whether you believe the current PMTCT programme has successfully or unsuccessfully delivered integrated services?
[Prompt: Can you provide some specific examples?]
8. Can you tell me about any experiences you have had in providing integrated PMTCT care
9. What are some of the lessons you have learned in providing integrated PMTCT care?
10. What kind of support – for example, managerial, clinical, staffing, lab, IT, etc. do you feel you need to provide integrated PMTCT care? What is absolutely essential, what can you do without, what is nice to have?
11. How easy do you think it would be to provide a more integrated PMTCT programme, if a facility wished to do so? Please explain.
12. Can you please tell me what your suggestions and feedback would be to someone who was thinking of setting up an integrated PMTCT programme?
13. Do you have any questions for me?

Thank you very much for your time

APPENDIX 2: STEPS OF THE THEMATIC ANALYSIS

Step 1. Code Material

- a) Devise a coding framework
- b) Dissect text into text segments using the coding framework

Step 2. Identify Themes

- a) Abstract themes from coded text segments
- b) Refine themes

Step 3. Construct Thematic Networks

- a) Arrange themes
- b) Select Basic Themes
- c) Rearrange into Organizing Themes
- d) Deduce Global Theme(s)
- e) Illustrate as thematic network(s)
- f) Verify and refine the network(s)

Step 4. Describe and Explore Thematic Networks

Step 5. Summarize Thematic Networks

Step 6. Interpret Patterns

APPENDIX 3: CONSENT FORM FOR STUDY PARTICIPANTS

This consent form was utilized in the primary study approved by the McCords Research Ethics Committee (see below). It is presented here for information only – since these interviews have already been conducted, and this study will consist of a secondary analysis of these transcripts (inter alia).

Consent to Participate in a Research Study

What is this study about?

It is a study about providing integrated PMTCT care at McCord Hospital

Why is this study being done?

This is a research study to learn more about the views, ideas, attitudes and experiences of role players / stakeholders regarding the realities and challenges of providing integrated PMTCT care.

Who is conducting this study?

The study is being carried out by Janet Giddy, Tamaryn Crankshaw and Lisa Butler as part of a CDC PMTCT Programme Evaluation.

Why am I being asked to take part in the study?

You are being asked to take part in this study because you played some role in the implementation of the PMTCT Programme at McCord Hospital.

How many people will take part in this study?

About 7 – 10 people involved with PMTCT care at McCord Hospital will be asked to take part in this study.

What will happen if I take part in this research study?

If you agree to participate in this study, the following will occur:

- You will be asked about your experiences with the PMTCT Programme
- You will be asked about your thoughts on the advantages and challenges of providing an integrated maternal and child health service
- The interview will be audio recorded, with your permission

How long will I be in the study?

The interview will last about one hour, at the most.

Are there any risks in taking part in this study?

There is the potential for loss of privacy or confidentiality. However, we will not collect any identifying information about you. Also, your answers to the questions will not be shared with your supervisor or any of your colleagues at the clinic. No personally identifiable information will be released in any form.

Your name will not be used in any report or publications from this study. All study data will be destroyed 5 years after publication.

Are there any benefits in taking part in this study?

There will be no direct benefit to you from taking part in this study. However, the findings of this research could be a benefit to other providers involved with PMTCT programmes.

What other choices do I have if I do not take part in this study?

You are free to choose not to take part in this study. If you decide not to take part in this study, there will be no disadvantage to you.

Will my information be kept private?

We will do our best to make sure that all information gathered from you for this study is kept private. However, we cannot guarantee total privacy. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. Your information will be identified only by a study number given to each person.

What are the costs of participating in the study?

You will not need to pay anything to take part in this study.

Will I be paid for taking part in the study?

You will not be paid for taking part in this study.

What are my rights if I take part in the study?

Taking part in this study is your choice. You may choose either to take part or not to take part in this study. If you decide to take part in this study, you may leave the study at any time i.e even after the interview you may contact me and ask that what you have discussed will not be included in the study. No matter what decision you make, there will be no negative consequences for you.

Who can answer my questions about the study?

You can talk to the researchers about any questions, concerns, or complaints you have about the study. Contact the researcher Dr. Janet Giddy at 083-9417818 or email janetgiddy@gmail.com.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the McCord Hospital Research Ethics Committee and speak with Dr Claire Kerry.

You will be given a copy of this consent form to keep.

NOTE: PARTICIPATION IN THIS RESEARCH IS VOLUNTARY.

You have the right to refuse to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

The project was read and explained to you clearly. Anything you did not understand was explained to you and all your questions were answered.

Do you wish to participate in this study?

YES ☐

NO ☐

Do you give permission for the interview to be audio recorded?

YES ☐

NO ☐

If you wish to participate in this study, you should sign below.

Date:

Name (Print):


Signature _____

Witness

Date

Name (Print)

APPENDIX 4: ETHICS APPROVAL - MCCORD HOSPITAL

	<table border="0"> <tr> <td>Tel: +27 31 268 5700</td> <td>28 McCord Road, Overport,</td> </tr> <tr> <td>Fax: +27 31 268 5705</td> <td>Durban, South Africa, 4001</td> </tr> <tr> <td colspan="2">.....</td> </tr> <tr> <td>Email: info@mccord.org.za</td> <td>PO Box 37587, Overport,</td> </tr> <tr> <td>www.mccord.org.za</td> <td>South Africa, 4067</td> </tr> </table>	Tel: +27 31 268 5700	28 McCord Road, Overport,	Fax: +27 31 268 5705	Durban, South Africa, 4001		Email: info@mccord.org.za	PO Box 37587, Overport,	www.mccord.org.za	South Africa, 4067
Tel: +27 31 268 5700	28 McCord Road, Overport,										
Fax: +27 31 268 5705	Durban, South Africa, 4001										
.....											
Email: info@mccord.org.za	PO Box 37587, Overport,										
www.mccord.org.za	South Africa, 4067										

27 June 2012

McCord Research Ethics Committee (MREC)
SA NHREC registration number: REC-170408-002
IRB00005803

Dear Dr Crankshaw

I refer to your application for ethics review of your research protocol. Your protocol was reviewed at the MREC meeting on 7th May 2012. I have the pleasure in informing you that the following study has now been approved.

PROJECT TITLE: Impact and Implementation of the Mamanengane Programme for Integrated Postnatal PMTCT, HIV and MCH Care, Durban, South Africa

STUDY NUMBER: 070512/6.3 tc

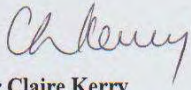
INVESTIGATOR (S): T Crankshaw (applicant)
T Govender
J Giddy
G Rutherford
L Butler
J Martin

MREC DATE APPROVED: 27 June 2011

DECISION OF COMMITTEE: Full approval

Please note that any changes/ amendments to your protocol must be reviewed and approved before being implemented. May we wish you every success in your research.

Sincerely



Dr Claire Kerry
Research Coordinator, McCord Hospital

Non Profit Company
Non Executive Directors: Prof P Zulu (Chairman) • Mr R Field (Vice-Chairman) • Dr K Wimble • Mr S van der Merwe • Mr P Campion • Ms T Tsautse • Dr J Reddy
Executive Directors: Dr H Holst (CEO) • Mr K Smith (CFO) • Mr P Zulu (HR Director)

P.B.O. No: 930031668 • Fundraising Authority: 06 600386 000 9 • Hospital Practice No: 5703808 • Vat No: 4330101355 • Company Reg No: 2000/022491/08

APPENDIX 5: ETHICAL APPROVAL – UCT



UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee



Room E52-24 Old Main Building
 Groote Schuur Hospital
 Observatory 7925
 Telephone [021] 406 6338 • Facsimile [021] 406 6411
 Email: shuretta.thomas@uct.ac.za
 Website: www.health.uct.ac.za/fhs/research/humanethics/forms

11 December 2014

HREC REF: 850/2014

Dr J Olivier
 Public Health & Family Medicine
 Falmouth Building

Dear Dr Olivier

PROJECT TITLE: HOW TO MAKE THE IDEAL OF INTEGRATION A PRACTICAL REALITY: THE PREVENTION OF MOTHER TO CHILD TRANSMISSION OF HIV (PMTCT) PROGRAMME AT MCCORD HOSPITAL, DURBAN- (Masters candidate- J Giddy)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30th December 2015.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF in all your correspondence.

We acknowledge that the student, Janet Giddy will also be involved in this study.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.

Institutional Review Board (IRB) number: IRB00001938

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP) and Declaration of Helsinki guidelines.

HREC 850/2014

APPENDIX 6: JOURNAL AUTHOR GUIDELINES FOR HEALTH POLICY AND PLANNING

Information for Authors

Health Policy and Planning's aim is to improve the design and implementation of health systems and policies in low- and middle-income countries through providing a forum for publishing high quality research and original ideas, for an audience of policy and public health researchers and practitioners. HPP is published six times a year.

HPP has a double-blinded peer-review policy. All papers, in each of the categories described below, are peer reviewed.

Specific objectives are to:

- Attract high quality research papers, reviews and debates on topics relevant to health systems and policies in low- and middle-income countries;
- Ensure wide geographical coverage of papers including coverage of the poorest countries and those in transition;
- Encourage and support researchers from low- and middle-income countries to publish in *HPP*;
- Ensure papers reflect a broad range of disciplines, methodologies and topics;
- Ensure that papers are clearly explained and accessible to readers from the range of disciplines used to analyse health systems and policies; and
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- original articles
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- methodological musings
- research in practice
- commentaries
- papers in our series 'How to do (or not to do)...' [for example, see Hutton & Baltussen, HPP, 20(4): 252-9] and
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